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Defibrillator Use and Maintenance In Massachusetts Hospitals and Ambulance Services

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Prepared by:

**Massachusetts Department of Public Health
Division of Health Care Quality**

Prepared for:

**U.S. Department of Health & Human Services
Food and Drug Administration**

May 1988

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DEFIBRILLATOR USE AND MAINTENANCE IN MASSACHUSETTS HOSPITALS AND AMBULANCE SERVICES

FINAL REPORT

Prepared by:

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
Division of Health Care Quality
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Prepared for:

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville, Maryland 20857

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May 1988

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I wish to acknowledge in particular James Nickerson who is the primary author of the report and coordinated the project. I wish also to acknowledge Kenneth Leary who conducted the field site visits and assisted in the project in all phases. Acknowledgements are due David Harrington and staff of the New England Medical Center's Biomedical Engineering Department who assisted in the survey protocol development as well as graciously providing technical assistance.

Finally, I would like to extend our appreciation to all of the hospital and ambulance service staff that participated in the study.

Irene R. McManus, M.P.H.
Director
Division of Health Care Quality

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EXECUTIVE SUMMARY

Defibrillator Use & Maintenance In Massachusetts Hospitals and Ambulance Services

The U.S. Food and Drug Administration (FDA) and the Massachusetts Department of Public Health (MDPH) collaborated on a survey of defibrillation equipment to determine the types of problems and deficiencies defibrillator systems and equipment have been displaying as well as to identify user related problems.

The FDA's Center for Devices and Radiological Health was interested in an assessment of user related practices due to the high level of adverse incidents involving the use of defibrillators received through the Medical Device Reporting (MDR) System. The reports suggested that many problems were user related, and specifically battery related.

The survey included visits to 30 hospitals and paramedic ambulance services throughout Massachusetts. The survey protocol included questions on general facility maintenance and continuing education, interviews of staff regarding preventative maintenance practices and problems with units, and a test of the battery capacity of selected defibrillator units.

A total of 97 units were tested and 76 device users (nurses and paramedics) were interviewed. The unit test found a 19% failure rate with respect to performance to specification. 67% of these failures resulted from battery related problems. Similarly, the most frequent reported problems encountered by users were battery related.

In general, defibrillator failures due to engineering or technical problems were rare. Rather most unit failures were related to user understanding and maintenance, specifically battery maintenance. The most prevalent problems in the prehospital setting were battery failure resulting from built up memory and physical abuse of equipment.

Accordingly, the following recommendations to improve defibrillator use were suggested:

- improve staff education and require user credentialing beyond ACLS;
- establish regular schedules for unit maintenance and standardized procedures or protocols for unit testing; and
- develop protocols to encourage users to report problems to the FDA.

These findings will assist the FDA by clarifying the reasons for the high level of MDR reports. The findings will also guide MDPH in developing appropriate standards for the overall safety and efficacy of the units in hospitals and ambulance services. Finally, the information collected in this study will provide policy direction to MDPH in expanding the scope of the use of defibrillators in the prehospital environment. These combined efforts will reduce the frequency of injuries and deaths associated with defibrillators.

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I. INTRODUCTION

The modern defibrillator came into being in the 1960s and has now been in use over 25 years. The cardiac defibrillator is an electronic appraratus used to terminate ventricular fibrillation by the application of brief electric shock to the heart via paddle electrodes to the patient's chest. The defibrillator accepts a charge from an AC power line or battery source, stores it, and delivers the energy in a short, controlled burst to the patient. Most units are battery powered so that they can be used during transport within a hospital or in an ambulance, or carried in the field.

Defibrillators are critical resuscitation instruments. Their failure to perform effectively may result in the death of a patient undergoing resuscitation or cause further cardiac damage or death in a patient undergoing elective cardioversion or emergency cardioversion of a life-threatening arrhythmia.

Failure to successfully defibrillate a patient may occur for a number of reasons, including inadequate pre-defibrillation cardiopulmonay resuscitation (CPR) technique; operator error; or depleted or defective batteries. There is no time to troubleshoot or correct even minor difficulties during emergencies, since every minute of delay dramatically decreases the probability of a successful resuscitation attempt.

Traditionally, defibrillation has been a restricted skill, only allowed to be performed by hospital emergency room personnel and highly trained paramedic personnel. Since the leading cause of death in adults is cardiovascular disease, in particular out-of-hospital cardiac arrest (heart attack), and the only definitive treatment is early defibrillation using a cardiac defibrillator, the use of defibrillators has expanded in the pre-hospital care arena. In many states, basic life support emergency medical technicians are now authorized to operate both manual and automatic cardiac defibrillators with minimal training.

With the advent of this relatively new concept in the pre-hospital care arena, coupled with the advances in technology of automatic and semi-automatic defibrillators, it is important to have solid baseline information on the scope of training and maintenance necessary to ensure the safe operation of defibrillators.

II. OBJECTIVE

The Massachusetts Department of Public Health's Division of Health Care Quality is responsible for regulating and monitoring the quality of care provided by health care facilities and services in the Commonwealth including hospitals and ambulances.

The purpose of the hospital program is to protect the health and safety of hospital patients through development of appropriate state standards, efficient and effective inspections, and enforcement. The Division currently licenses approximately 157 hospitals. Similarly, the ambulance program seeks to protect the health and welfare of Massachusetts residents who require ambulance services through the development of appropriate state standards for efficient and effective inspection, consultation, and enforcement. The Division currently licenses 308 ambulance services, 46 of which provide advanced life support at the paramedic level. Also, nine hospital based paramedic units have defibrillation capability. In addition, since 1983, the Division has sponsored two EMT-Defibrillation special projects which allow manual and automatic defibrillation by intermediate and basic emergency medical technicians respectively.

The "Defibrillator Use/ Maintenance Investigation" study allows the Division to expand upon the scope of these regulatory programs by developing appropriate standards and identifying specific needs for further regulatory action. Specifically, the objective of this study was to assess defibrillator users and their interactions with the device and attendant problems. The assessment was accomplished through the gathering of very specific information on operator training related to the use of defibrillators; user practices related to the maintenance of defibrillators; and problems in use caused by the working environment.

III. METHODOLOGY

The "Defibrillator Use/ Maintenance Investigation" study was divided into two phases. The first phase, which began in September 1986, included training, development of the intended protocol, and a trial of the intended survey protocol at a hospital and an ambulance service. The second phase, which began in August 1987, included completing site visits at 15 hospitals and 15 ambulance services to gather specific information using the protocol, data summary and analysis, and a final report summarizing findings and recommendations.

A. PHASE I

1. Training

The Center for Devices and Radiological Health hosted a two day training session for specific instruction and information on the use and operation of defibrillators; battery maintenance and testing; problems associated with defibrillators; operation of defibrillator testers; the device experience network (DEN) reporting system; and the mandatory device reporting (MDR) system. Upon returning from the training session, the project coordinator met with the field investigator and biomedical engineer to disseminate the information.

2. Development of Survey Protocol

A survey protocol was developed by project staff following the training session. The protocol was designed to present a representative picture of the condition of defibrillator usage and maintenance in Massachusetts hospitals and ambulance services. The survey document was designed to collect information including: a) operator training related to use of defibrillators; b) user practices related to preventative and corrective maintenance; c) problems in use caused by the working enviornment or component failure; and d) machine specific test data.

3. Test of Draft Protocol

The draft survey protocol was tested at a large teaching hospital and a private paramedic ambulance service. The survey protocol was finalized following the field test and comment from the FDA.

B. PHASE II

1. Data Collection - Field Site Visits

The 15 hospitals and 15 paramedic services were randomly selected and surveyed from each of the six EMS regions in the state. Participation was on a voluntary basis and three did not agree to participate, however, these were replaced by three additional facilities. Upon gaining interest facilities/ services were forwarded an introductory letter and overview of the study. Copies of the letters to facilities/ services is included as Appendix A.

The final survey document contained three parts. The first part was the "Facility/ Service Overview" which included general information on the facility profile, continuing education, and defibrillator battery maintenance. The field investigator questioned administration, staff educator, and the biomedical engineering or operations manager to complete this form. The second part was the "Field Surveyor Test Form" which included information on defibrillator battery support systems, the energy test, and unit inspection. The field investigator completed one of these forms for each unit inspected.

The third part was the "Professional Staff Interview" and included information on defibrillator battery maintenance, accessories, and general problems with defibrillators. The form was completed by professional supervisory staff in the various areas surveyed. A copy of the survey document is included as Appendix B.

2. Data Evaluation and Reporting

Appropriate summary distributions and statistics were compiled and are described in narrative in Section IV of this report. The narrative is orgainized by the survey protocol format and focuses on the research questions of particular interest to the FDA.

The findings and recommendations are based upon problems found in the surveyed hospitals and ambulance services, and any characteristics of facilities found to be associated with the problems. Also, the field investigators general impressions and recommendations are included.

3. Conference

The Department sponsored a conference to share the findings and recommendations of the study with the hospitals and ambulances services that participated in the study and other interested parties.

The half-day conference was held on April 7, 1988 at Tufts New England Medical Center in Boston and presented the results of the Massachusetts investigation and offered recommendations for improved equipment maintenance and operator training based on the survey findings. The conference also included historical background on the invention of the defibrillator, results from other state studies of defibrillating equipment, and a preview of the clinical applications for future defibrillating devices.

The conference was designed for people who are responsilble for the maintenance and operation of defibrillators, including paramedics, biomedical engineers, equipment maintenance managers, ambulance service operation managers, nurses and physicians. The conference was attended by approximately 100 people. Copies of the conference materials is included as Appendix C.

IV. FINDINGS

A. Part I- Hospital/ Ambulance Service Overview

1. General Information

A total of 15 hospitals and 15 paramedic level ambulance services were visited. The hospital group included eleven acute care hospitals and four trauma centers. The average bed size of the facilities surveyed was 358, with a range of 115 to 1000. The paramedic services included eight private ambulance services, two municipal fire departments, three hospital based paramedic services, one municipal hospital paramedic service, and one helicopter/ medevac service (see Appendix D, Figure 1). The average number of paramedic response vehicles at the ambulance services surveyed was three, with a range of one to four.

A total of 97 defibrillator units were tested during the survey. This sample included 70 of the 347 defibrillators operational in hospitals (20%), and 27 of the 44 units operational in ambulance services (61%) (see Figure 2). The defibrillator units surveyed in hospitals were found in five different locations. 18 (26%) were used in emergency departments, 18 (26%) in intensive care units, 11 (16%) in coronary care units, 5 (7%) in operating rooms, and 18 (26%) in other medical units (see Figure 3).

68 of the units surveyed (70%) were manufactured by Physio Control, 18 (20%) by Hewlett-Packard, five (5%) by Datascope, two (2%) by Electrodyne, two (1%) by Pulsar, one (1%) by Honeywell, and one (1%) by Cardiopak (see Figure 4). Virtually all (96%) paramedic units used Physio Control Lifepak 5's. Of the Physio Control models surveyed in hospitals 29 (43%) were Lifepak 5, 21 (31%) Lifepak 6 or 6S, 8 (12%) Lifepak 8, 5 (7%) Lifepak 7, 2 (3%) Lifepak 4, 2 (3%) Model 640 (AC), and 1 (1%) Lifepak 1 (see Figure 5).

2. Continuing Education

In general, continuing education is most often conducted on a annual or semi-annual basis by both hospitals and ambulances, however, it is usually done as part of an ACLS course, not as a specific defibrillator program. 41% of the hospitals reported conducting continuing education or inservice programs on an annual basis, 17% monthly, 17% quarterly, 17% never, and 8% other. 46% of the ambulance services reported conducting continuing education on a semi-annual basis, 36% annually, 9% monthly, and 9% other. (see Figure 6). Both hospitals and ambulances reported that in-house training was given on newly acquired devices. Also, staff reported being comfortable in operating the equipment after the training.

Our impressions from conducting the field surveys is that in hospitals, the nursing staff-- while knowing how to operate the equipment-- had little knowledge of the battery capabilities and precautions and/ or general equipment maintenance. The nursing staff identified the charge or head nurse as usually having more understanding. We have no data to substantiate these impressions. Also, continuing education components are geared toward the nursing staff and not physician users. Some hospitals did not routinely credential or train staff in defibrillator use, electing instead to aggressively credential identified "code teams."

3. Maintenance Information

22 of the 30 facilities and services surveyed (10 hospitals and 12 ambulance services) answered the preventative maintenance question. Of these facilities, all reporting hospitals and 75% of reporting ambulance services provided preventative maintenance. (see Figure 7). 46% of hospitals provided preventative maintenance on a quarterly basis, 36% on a semi-annual basis, and only 18% on a monthly basis. By contrast, 37% of ambulance services provided preventative maintenance on an annual basis, 25% on a quarterly basis, 13% on a monthly basis, 13% on a semi-annual basis, and 13% other (see Figure 8).

Most hospitals reported that the maintenance was performed in-house by the biomedical engineering department, whereas ambulance service preventative maintenance was performed most frequently by the manufacturer.

Battery maintenance within the hospitals varied greatly, with some having strict reconditioning procedures while others had no procedures. Only 44% of the hospitals reported completely discharging batteries prior to recharge, whereas 75% of ambulance services reported such deep discharge (see Figure 9). These differences between the hospitals and ambulance services were not statistically significant ($X^2 = 1.26$, n.s.). 67% of the ambulance services reported having monthly battery cycling procedures, whereas 67% of hospitals reported cycling on an annual basis, replacement as necessary, or never.

B. Part II- Unit Inspection

Seventy-three (81%) of the defibrillators tested performed to specifications. Seventeen (19%) of the units tested did not perform to specification (see Figure 10). These rates of failure were virtually identical in both hospitals and ambulance services. The types of problems included battery failure (20%), unit failure (20%), slow charging cycle (47%), and other (13%) (see Figure 11). Again, the types of problems were almost identical in both the hospitals and ambulance services. One unit delivered a different charge from that of the setting.

Seventy-six (88%) of the units tested did not have an instructional manual accompanying the unit, with only 10 (12%) having manuals with the units.

Commonly seen defects included frayed cable leads, broken monitor to defibrillator clasps, broken terminal pins and cracked carrying cases. Also, some older units were found to have a maximum setting of only 312 joules. Although these units performed to their specifications, the current American Heart Association (AHA) Advanced Cardiac Life Support (ACLS) standards require higher delivery and discharge settings.

Several of the battery failures on units that use charging caddie trays were due to poor plug contact. Only one device had an audible alarm for poor charging. Also, it was evident that most hospitals cycled the older equipment from heavy use areas (i.e. CCU, ED) to less busy areas (i.e. X-Ray). This practice results in the least trained or experienced personnel using the oldest and most prone to fail equipment.

C. Part III- Professional Staff Interview

A total of 76 professional staff were interviewed- 59 nurses and 17 paramedics. The professional staff interview reflects that the routine check out of equipment occurs more frequently at ambulance services. 72% of the paramedics reported checking equipment each shift and 18% on a daily basis. At hospitals 50% of the nursing staff reported checking equipment each shift and 43% on a daily basis. However, standardized procedures or protocols for unit testing are rare in both the hospital and ambulance services, and the procedure appears to be left to the whim of the user.

A majority (88%) of hospital staff reported that batteries are charged continuously. Ambulance service staff reported that battery charging occurs 33% of the time on a daily basis, 33% after the low battery light activates, 10% continuously, 5% after each use, and 19% other (see Figure 12).

Users were asked to indicate whether they had experienced equipment failures in the past year. The questionnaire included information on the types of failure and the frequency with which these failures occurred. Of the 59 nurses interviewed, 36% reported experiencing battery related problems at least once in the past year. These failures included either battery failure, no charge, or no power-up. 31% of the users reported experiencing unit malfunctions which included no synchronization, ECG display failure, pacing malfunction, charge/ no discharge, cord/ cable failure or paddle failure. 21% of the users reported encountering operator related problems such as operator error, no muscle response, skin burn arcing, or user shock (see Figure 13). Of the 17 paramedics interviewed, 65% reported experiencing battery related problems at least once in the last year, 53% reported unit malfunctions, and 24% reported operator related problems.

Many of the hospital staff also reported that no spare batteries are kept with the system for immediate use, whereas ambulance service staff reported one, two, or more batteries are kept with the unit.

97% of hospital and ambulance service staff reported no problems with synchronized cardioversion (see Figure 14).

When users were asked to describe actual or potential problems that would be avoidable if the defibrillator units were redesigned, defibrillator users responses included:

- lighter and smaller units;
- longer cords;
- extended battery life;
- cardioversion instructions on the unit;
- faster charging time to maximum joules;
- make stronger battery prongs;
- make stronger buttons on paddles;
- units that are less sensitive to artifact while transporting.

When users were asked to identify actual or potential problems that might have been avoided with better written instructions from the manufacturer, better markings, or better training responses included:

- more frequent inservices (especially for interns);
- defibrillator certification;
- brief instructions on device;
- instructions need to be less technical, more brief and easy to follow;
- more instructions on operation of synchronization.

V. CONCLUSIONS AND RECOMMENDATIONS

The study has focused on two interrelated questions: first, the quality of training and maintenance of defibrillators in facilities and second, user related practices of unit testing and types of problems users encounter in the working environment. In addition, testing the battery capacity of the units allowed an assessment of the actual condition of a representative sample of defibrillator units in hospitals and ambulance services.

The major findings may be summarized as follows:

- staff education is limited and usually a part of the bi-annual ACLS certification;
- approximately one in five of the defibrillator units tested did not perform to specification-- the majority due to battery related problems; and
- approximately one-third of hospital staff and two-thirds of ambulance service staff encountered battery related problems at least once a year.

These findings suggest a need for more frequent user education programs, specifically designed to review appropriate maintenance practices and device limitations. The high failure rate of units tested and high proportion of users encountering battery related problems in the field also suggest that facility/ service battery maintenance and checkout procedures are inadequate.

Therefore, the following recommendations are suggested:

- Instruction - require user credentialing beyond ACLS. Incorporate device checkout into annual BLS/CPR recertification.
- Unit and Battery Preventative Maintenance - incorporate regular preventative maintenance schedules as part of risk management.
- Unit and Battery Regular Testing - establish standardized procedures or protocols for daily unit testing. Each hospital and ambulance service should have standardized written policies for staff on testing units daily.
- Reporting - development of protocols to encourage users to report problems to the FDA. Each ambulance and hospital should have mechanisms for written complaints and incident reports.
- Research - continue advancing research on future applications of defibrillating technology. Design units more adaptive to appropriate environments.

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APPENDIX A: LETTERS

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
Division of Health Care Quality
80 Boylston Street
11th Floor
Boston, 02116

Deborah Prothrow-Stith, M.D.
Commissioner

AMBULANCE SERVICE

Dear

Thank you for agreeing to participate in the Department of Public Health's Defibrillator Study.

Enclosed is a brief description of the purpose of the study and the type of information that will be collected during the survey.

As I indicated, we will need staff available to respond to questions concerning general service overview of defibrillator/battery maintenance and continuing education. In addition, the field surveyor will need to test the battery capacity of defibrillators in your Paramedic unit(s). The test of the battery capacity will take no longer than ten minutes. Also, we request that a paramedic supervisor be available to respond to questions concerning equipment checking, battery charging, and any problems encountered with defibrillators. The professional staff interview will take approximately 20 minutes. We anticipate that the survey will take no longer than 2 hours to administer.

We have scheduled your service for a filed visit on ________________________. Mr. Kenneth Leary is the field surveyor for the project.

All information collected will be held in strict confidence, and your service's name will not appear in the final report to the FDA.

If you have any questions, please do not hesitate to contact me at 617-727-5860.

Again, thank you very much for your interest and cooperation.

Sincerely,

James Nickerson
Project Coordinator

cc: Kenneth Leary, Field Surveyor

Enclosure

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
Division of Health Care Quality
80 Boylston Street
11th Floor
Boston, 02116

Deborah Prothrow-Stith, M.D.
Commissioner

HOSPITAL

Dear

Thank you for expressing interest in participating in the Department of Public Health's Defibrillator Study.

Enclosed is a brief description of the purpose of the study and the type of information that will be collected during the survey.

As I indicated, we will need staff available to respond to questions concerning general facility overview of defibrillator/battery maintenance and continuing education. In addition, the field surveyor will need to test the battery capacity of defibrillators in five of your units - emergency room, intensive care unit, coronary care unit, operating room, and a general medical floor. The test of the battery capacity will take no longer than ten minutes per unit. Also, we request that a nursing supervisor of the unit where the defibrillator is located be available to respond to questions concerning equipment checking, battery charging, and any problems encountered with defibrillators. The professional staff interview will take approximately 20 minutes. We anticipate that the survey would take approximately 3-4 hours to administer.

All information collected will be held in strict confidence, and your facility name will not appear in the final report to the FDA.

We would like to schedule your facility for a field visit sometime in ________________________. Please contact me at your convenience to set a date. I can be reached at 617-727-5860. Also, if you have any questions please do not hesitate to call.

Again, thank you very much for your interest and cooperation.

Sincerely,

James Nickerson
Project Coordinator

cc: Kenneth Leary, Field Surveyor

The Commonwealth of Massachusetts

Executive Office of Human Services
Department of Public Health

Division of Health Care Quality

80 Boylston Street

11th Floor

Boston, 02116

Deborah Prothrow-Stith, M.D.
Commissioner

Dear

I would like to take this opportunity to thank you for participating in the Department of Public Health's Defibrillator Study.

Also, please extend my thanks to your staff for the courtesy they showed the field surveyor while administering the survey protocol.

Massachusetts is one of five states participating in this FDA project. We expect that the collective findings from all the states will improve defibrillator use and maintenance. The Department plans to sponsor a conference to share these findings. I will notify you when we have a specific date.

If you have any further questions, you may contact me at 617-727- 5860.

Again, thank you very much for your interest and cooperation.

Sincerely,

James Nickerson
Project Coordinator

cc: Kenneth Leary, Field Surveyor

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
Division of Health Care Quality
80 Boylston Street
11th Floor
Boston, 02116

BAILUS WALKER, Jr., Ph.D., M.P.H.
Commissioner

DEFIBRILLATOR USE/ MAINTENANCE INVESTIGATION

OVERVIEW OF STUDY

The U. S. Food and Drug Administration (FDA) and the Massachusetts Department of Public Health are collaborating in conducting a survey of defibrillation equipment to determine the types of problems and deficiencies these systems and equipment have been displaying.

BACKGROUND

Defibrillator adverse incident reports have been received through the Medical Device Reporting (MDR) System at a fairly constant rate over the past year. This level of reporting has caused concern at the FDA, Center for Devices and Radiologic Health (CDRH). A task force has been set up by CDRH to look at manufacturing/ design problems by surveying the manufacturing establishments and looking at their complaint files, manufacturing practices, design practices, and testing. It has been suggested that many of the problems in the defibrillator area are user related. Some of these user related problems could be due to poor maintenance (both corrective and preventative), lack of functional understanding of the device, abusive environment and handling, and the emergency nature of use which may exacerbate human factor related design limitations of the device.

DEFIBRILLATOR SURVEY PROTOCOL

The Survey Protocol is designed to collect information in order to present a represenatative picture of the condition of the defibrillator usage and maintenance in Massachusetts hospitals and ambulances.

The information to be collected includes:

- Operator training related to use of defibrillators-
  - Source of Training
  - Nature of Training
  - Intitial/ Continuing
  - Extent of training

User practices related to-
  - Preventative maintenance
  - Corrective maintenance
  - Spare battery packs
  - Back-up defibrillators
  - Recharging of batteries
  - Replacement of battery packs
  - Functional check out of devices

Problems in use caused by-
  - Errors in operation
  - Component failures
  - Working environment

Also, to determine the level of maintenance, the field surveyor will check the accuracy of energy delivered and other selected parameters using a defibrillator tester.

It is anticipated that the data collection from the hospitals and ambulance services will help clarify the reasons for the high level of MDR reports and assist FDA in developing a course of action to ameliorate the problem.

The Department plans to hold a conference at the conclusion of the study to share the findings and any recommendations with those hospitals and ambulance services that participated in the study as well as any other interested parties.

FOR FURTHER INFORMATION

If you have any further questions about the study or would like a copy of the final results please contact James Nickerson, Project Coordinator, Massachusetts Department of Public Health, at 617-727-5416.

Thank you for your interest and cooperation.

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
Division of Health Care Quality
80 Boylston Street
11th Floor
Boston, 02116

Deborah Prothrow-Stith, M.D.
Commissioner

Circular Letter: DHCQ 10-87-207

TO: Administrators of:

Hospitals
Ambulance Services

FROM: Irene R. McManus, M.P.H.
Director
Division of Health Care Quality

DATE: October 9, 1987

SUBJECT: Defibrillator Batteries

****

The U.S. Food and Drug Administration (FDA) and the Massachusetts Department of Public Health are collaborating in conducting a "Defibrillator Use/ Maintenance Investigation" study which will assess the quality of defibrillator equipment and training in Massachusetts hospitals and ambulance services.

In connection with this study the FDA, Center for Devices and Radiological Health (CDRH) is exploring the problem of defibrillator malfunctions and in particular battery maintenance and battery failure.

During a recent investigation of an older Physio Control Lifepak 5 battery by the FDA, CDRH, Office of Science and Technology, the battery died without warning. Upon examination it was found that one of the internal mechanical connections had brocken. The FDA would like to further examine this problem and its prevalence.

In order for the FDA to continue their investigation, the FDA would like to collect and evaluate as many used (probably failed) batteries as possible for mechanical and electrical failures. The FDA has asked state health departments to contact hospital and ambulance services to ask the facilities to send old defibrillator batteries, particularly Lifepak 5 batteries, that would otherwise be discarded. The FDA is only asking for those batteries that are no longer usable and would otherwise be thrown away. The facilities that send in discarded batteries will be notified of the results of the testing and evaluations.

Please send the used defibrillator batteries to:

Nancy A. Flynn
Biomedical Engineer
Therapeutic and Life Support Devices Branch
Office of Training and Assistance
Center for Devices and Radiological Health
Food and Drug Administration
U.S. Department of Health & Human Services
Rockville, Maryland 20857
(Telephone: 301-443-2436)

If you have any questions regarding the study please contact James Nickerson, Project Coordinator, Massachusetts Department of Public Health, at 617-727-5416.

Thank you very much for your help and cooperation.

APPENDIX B: SURVEY PROTOCOL

U.S. FOOD and DRUG ADMINISTRATION/
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

DEFIBRILLATOR USE/ MAINTENANCE INVESTIGATION SURVEY PROTOCOL

Hospital/ Ambulance Service: Address:	DHCQ ID #: Date:
Contact Person:	Time In:
Telephone Number:	Time Out:

FACILITY/ SERVICE OVERVIEW

A. GENERAL INFORMATION

1. Facility/ service type: ______________________

size: ___________

2. Approximately how many defibrillators are operational at your facility/ service? _______

3. What is the number of staff listed below which use the defibrillator and the percent of time by each group?

	Number	Percentage (total=100%)
Physicians	______	______
Physician Assistants	______	______
Nurses	______	______
Paramedics	______	______
Other professional staff	______	______
(specify) ________________		

4. Have you ever reported a problem with a defibrillator to:

		Frequency
_____	FDA	________
_____	State	________
_____	Manufacturer	________
_____	Emergency Care Research Institute	________
_____	Other (specify) __________________	________

B. EDUCATION

1. Frequency of Defibrillator inservice/ continuing education

_____ Never
_____ Monthly
_____ Quarterly
_____ Semi-annual
_____ Annual
_____ Other (specify)
____

2. Source of defibrillator ongoing/ continuing education (check all that apply)

_____ Employer/ education instructor
_____ Sales representative
_____ Manufacturer (specify)
____
_____ Outside education seminar
_____ ACLS

3. Type of inservice (check all that apply)
_____ Lecture _____ Demonstration
_____ Hands on _____ Other (specify)
____

4. Average length of inservice? (hours) _______

5. Is in-house training given on newly acquired devices?
______ Yes _____ No

After training did staff feel comfortable in operating equipment?
______ Yes _____ No

C. MAINTENANCE INFORMATION

Defibrillator/ monitor maintenance:

1. Is there a routine preventative maintenance schedule?
_____ Yes ____ No
If yes, frequency: _____ Monthly
_____ Quarterly
_____ Semi-annual
_____ Annual
_____ Other (specify)
____

2. Who provides the maintenance?
____ Manufacturer
____ Independent Contractor
Does the contractor provide written documentation of all worked performed? ____ Yes ____ No _____ unknown
____ In-house
____ Biomedical Eng. Dept.
____ Maintenance
____ Other (specify)
____

If maintained in-house, have technicians been able to maintain the equipment based on instructions from the manufacturer? ____ Yes ____ No

If maintained in-house, are repairs performed:
_____ in-house
_____ outside

Are service and repair records on file? ____ Yes ____ No

Battery maintenance:

3. When are the batteries reconditioned?
______ Monthly
______ Quarterly
______ Semi-annual
______ Annual
______ Other (specify)
____

4. How are the batteries reconditioned?

5. Are batteries completely discharged prior to recharge?
______ Yes ______ No

FIELD SURVEYOR TEST FORM

Location of defibrillator unit tested ______________________________
(ER/ ICU/ CCU/ OR/ other major unit- specify)

A. GENERAL DEFIBRILLATOR/ BATTERY SUPPORT SYSTEM INFORMATION

1. Defibrillator
   Manufacturer/ Model ____________________________
   Serial Number ____________________________

2. Monitor
   Manufacturer/ Model ____________________________
   Serial Number ____________________________

3. Battery Pack
   Manufacturer/ Model ____________________________
   Serial Number ____________________________

4. Battery Charger ( ) built in ( ) external
   Manufacturer/ Model ___________________________
   Serial Number ___________________________

5. Battery Exercise/ Analyzer ( ) none present
   Manufacturer/ Model ___________________________
   Serial Number ___________________________

6. Type of batteries:
   _____ NiCad
   _____ Gel Cell
   _____ Lithium
   _____ Other (specify) ___________________________
   _____ Unable to determine

7. Type of power source: (check)
   Portable battery powered _______
   Non-portable line (a/c) powered _______
   Battery and line powered _______

B. ENERGY TEST

	Defibrillator Setting	Delivered energy:		
		First	Second	Third
1. Line powered:				
Low (0-100)	____________	_______	_______	_______
Medium (100-300)	____________	_______	_______	_______
High (300+)	____________	_______	_______	_______
2. Battery powered:				
Low (0-100)	____________	_______	_______	_______
Medium (100-300)	____________	_______	_______	_______
High (300+)	____________	_______	_______	_______

C. UNIT INSPECTION

1. Does the defibrillator perform to specifications?
____ Yes ____ No
If no, why?
____ Battery Failure ______ Unit Failure
____ Slow Charging Cycle ______ Other
(specify) _______________

2. Are the paddles:
Pitted ______ Yes ____ No
Clean ______ Yes ____ No

3. Is the scope intact?
______ Yes ______ No _______ N/A

4. Is the strip chart functional?
______ Yes ______ No _______ N/A

5. Are strain reliefs and cables intact?
_______ Yes ______ No

6. Do the indicator light and operating switches work?
_______ Yes ______ No

7. When the unit is not in use, is it exposed to:
Heat/ Cold ______ Yes ______ No
Dust ______ Yes ______ No
Sunlight ______ Yes ______ No

8. Does an instruction manual accompany the unit?
_______ Yes _______ No

9. List any noticeable defects or problems:

(Attach strip here)

DHCQ Facility/ Service ID# __________

PROFESSIONAL STAFF INTERVIEW

A. DEFIBRILLATOR INFORMATION

1. Where is the unit located/stored? ______________________________

2. Is a checklist maintained to assure that the unit is functional before each use?

	Yes	No
Defibrillator	_____	_____
Monitor	_____	_____
Batteries	_____	_____

Who is in charge of checking the equipment? __________________

3. How often is the equipment checked?

	Shift	Daily	Monthly	Never	Other (specify) ________________
Defibrillator:	____	____	____	____	_____
Monitor:	____	____	____	____	_____
Batteries:	____	____	____	____	_____

4. Average time the defibrillator is used
_______ per week _______ per month ______ annual

5. Is the defibrillator a,
_____ Primary device
If the device is primary, are there designated back-up defibrillators to this unit?
_____ Yes _____ No
If yes, how many? ________
Where are they located?

OR

_____ Backup device
If it is solely a backup device, does it receive the same performance inspection and maintenance/ servicing as a primary device?
______ Yes ______ No
If no, how does the performance inspection and maintenance differ?

5. Have any of the defibrillator components been modified?
______Yes _____ unknown
______No
If yes, how was it modified? (check below as appropriate)

	Electrically	Physically	Both
Defibrillator:	_____	_____	____
Monitor:	_____	_____	____
Battery Support System:	_____	_____	____

6. Is the instruction manual adequate for operation?
____ Yes ____ No

B. BATTERY INFORMATION

1. When are the batteries charged?
____ Continuously
____ After each use
____ After low battery indicator light comes on
____ Daily
____ Weekly
____ Other (specify)
____

2. How often is the battery tested?
______ Never
______ Daily
______ After each use
______ After low battery light activates
______ Other (specify)
____

How is it tested?

3. When is a battery pack discarded?
_____ After useful life expectancy
_____ No longer holds charge
_____ No longer holds charge after reconditioned
_____ Within an established time frame.
Specify timeframe _________

4. How many spare batteries are kept with this system for immediate use?
____ None
____ One
____ Two
____ More (specify)
____

5. Are battery packs trickle-charged until being removed from the charger?
____ Yes _____ No _____ N/A

6. Have you experienced any problems with rapid charging batteries?
______ Yes _____ No
If yes, explain

C. ACCESSORY INFORMATION

1. Have there been any problems with the synchronized shock capability of this unit?
_____ Yes _____ No
If yes, explain:

2. Have you experienced any problems with the defibrillator paddles of this unit?
______ Yes _____ No
If yes, list: Manufacturer/ Model _________________
Paddle size ______________ Inches/cm
Describe problem:

D. PROBLEMS WITH DEFIBRILLATORS

(Note: The following questions apply to all defibrillators.)

1. Have any of the following defibrillator problems caused by the work environment been reported? (check all that apply and estimate the number of times these problems have occured over the last year)

		Frequency	Notes:
____	Moisture	______	
____	Cold/ Heat	______	
____	Vibration	______	
____	Shock	______	
____	Electromagnetic interference effect	______	
____	Other (specify) ______________	______	

In general or unit specific:

2. Have any of the following defibrillator failures been experienced? (check all that apply and estimate the number of times these problems have occured over the last year)

		Frequency	Notes:
____	Battery failure	_______	
____	No charge	_______	
____	No muscle response	_______	
____	Skin burn arcing	_______	
____	No power-up	_______	
____	No Synch	_______	
____	ECG display failed	_______	
____	Pacing malfunction	_______	
____	Charge/ no discharge	_______	
____	User shock	_______	
____	Cord/ cable failure	_______	
____	Paddle failure	_______	
____	Operator (user) error	_______	
____	Other (specify) __________________	_______	

In general or unit specific:

3. Describe actual and potential problems that would be avoidable if the defibrillator were redesigned. (Include human-factor design problems, and/or component problems)

4. Identify any actual or potential problems that might have been avoided with better written instructions from the manufacturer, better markings, or better training.

5. Have you ever reported a problem with a defibrillator?
______ Yes ______ No
If yes, was it:
______ Verbal ______ Written
Where was it reported to (i.e. biomedical engineering)

6. Describe any other problem(s) with defibrillators/ monitors/ batteries other than those already mentioned? and-
THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS FORM.

(DHCQ Facility/ Service ID # _______)

The Commonwealth of Massachusetts

Executive Office of Human Services
Department of Public Health

Division of Health Care Quality

80 Boylston Street

11th Floor

Boston, 02116

JS WALKER, Jr., Ph.D., M.P.H.
Commissioner

DEVICE PROBLEM REPORT FORM

The purpose of this form is to inform you that while administering the Defibrillator Survey Protocol a problem was discovered with the following device:

LOCATION OF DEVICE: DATE:

DEVICE NAME: TIME:

SERIAL NUMBER:

PROBLEMS NOTED OR SUSPECTED:

FORM COMPLETED BY: ______________________
Field Surveyor

FORM LEFT WITH:

If you have any questions, please contact James Nickerson, Project Coordinator, at 617-727-5416.

APPENDIX C: CONFERENCE MATERIALS

Conference Goals

The purpose of this conference is to share the results of a statewide investigation of defibrillating equipment maintenance and operation. The survey was conducted by the Massachusetts Department of Public Health and was funded by the U.S. Food and Drug Administration.

The investigation identified specific problems with equipment maintenance and operation. Results and recommendations from the Massachusetts investigation will be presented, as well as the national perspective gained from other studies.

The half-day conference will also include background on the invention of the defibrillator and a preview of the clinical applications for future defibrillating technology.

Who Should Attend

This conference is designed for biomedical engineers, ambulance service operations managers, paramedics, hospital administrators, equipment maintenance managers, and nurses or physicians who are responsible for the maintenance and reliable operation of defibrillators.

Division of Health Care Quality
Department of Public Health
80 Boylston Street, Room 1100
Boston, MA 02116

PLEASE ROUTE TO THE FOLLOWING:	
	Ambulance Services
	Biomedical Engineering
	Equipment Maintenance
	Emergency Room
	Nursing
	Training and Development

What You Don't Know About Defibrillators:

Results of an Investigation into Defibrillator Maintenance and Operation

Thursday, April 7, 1988
Tufts New England Medical Center

Sponsored by
Massachusetts Department of Public Health
Division of Health Care Quality

Agenda

8:15 Check-In

8:45 **Welcoming Remarks**
James V. Divver
Assistant Commissioner
Bureau of Health Care Systems
Department of Public Health

Historical Background of Defibrillator
Paul Zoll, M.D.
Inventor of the Defibrillator

National Overview of Defibrillator Studies
Edward McDonald
New England District Director
U.S. Food and Drug Administration

Overview of Massachusetts Defibrillator Maintenance Investigation
James Nickerson
Policy Analyst, Emergency Medical Services
Division of Health Care Quality

10:00 **Break**

Results and Recommendations from Massachusetts Defibrillator Maintenance Investigation
Kenneth Leary
Director, Medic IV
Emergency Medical Services Project
Metropolitan Boston Hospital Council

David Harrington
Director, Medical Engineering
New England Medical Center

Future Technology: Clinical Applications
Patricia Kelly, M.D.
Electrophysiology Unit
Massachusetts General Hospital

12:00 **Adjourn**

Information

Registration

The registration fee is non-refundable. If you cannot attend the conference, you may send someone to take your place.

Conference registration will be closed when seating capacity is reached. Therefore, early registration is advised.

No confirmation of registration will be sent. Applicants will be notified only if the conference is full.

On the morning of the conference, you must check in at the registration desk to verify your registration.

Location

The conference will be held in DeBlois Auditorium B at Tufts University Medical School, 145 Harrison Avenue in Boston. The MBTA orange line stops at Tufts New England Medical Center.

Public parking is available nearby.

Continuing Education Units

Applications have been submitted to the following organizations:

Massachusetts Nurses' Association (MNA)
Office of Emergency Medical Services (OEMS)

Participants will receive certificates of attendance at the end of the conference.

For more information contact Claudia Reinhardt, Education and Training, Division of Health Care Quality (617) 727-5860.

Registration Form

The registration fee is $15 per person. Make your check payable to:

MHRI/DHCQ Education Fund

Please use a separate registration form for each participant.

Name____________________

Organization____________________

Address____________________

City____________________

State__________ Zip Code__________

Daytime telephone (_____)_______________

I would like CEU credit:

☐ Registered Nurse____________________
Social Security Number

☐ Paramedic____________________
Paramedic License Number

Mail your registration form and check to:

Massachusetts Health Research Institute
101 Tremont Street
Boston, MA 02108

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
Division of Health Care Quality
80 Boylston Street

Deborah Prothrow-Stith, M.D.
Commissioner

WHAT YOU DON'T KNOW ABOUT DEFIBRILLATORS:
Results of an Investigation into Defibrillator Maintenance & Operation

Thursday, April 7, 1988

8:45	**Welcome** James V. Divver Assistant Commissioner Bureau of Health Care Systems/Dept. of Public Health
9:00	**Historical Background of the Defibrillator** Paul M. Zoll, MD Inventor of the Defibrillator
9:20	**National Overview of Defibrillator Studies** Phillip Piasecki, MS, MBA Deputy Director, Investigations Unit U.S. Food and Drug Administration
9:40	**Overview of the Massachusetts Investigation** James Nickerson Policy Analyst, Emergency Medical Services Division of Health Care Quality/Dept. of Public Health
10:00	**Break**
10:15	**Findings & Recommendations from the Massachusetts Investigation** Kenneth Leary, BSN, MS Director, Medic IV Emergency Medical Service Project Metropolitan Boston Hospital Council David Harrington, MBA Director, Medical Engineering New England Medical Center
11:05	**Future Technology: Clinical Applications** Patricia Kelly, MD Cardiac Electrophysiology Unit Massachusetts General Hospital
11:45	**Final Question and Answer Session**
12:00	**Adjourn**

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
150 Tremont Street
Boston 02111
617-727-2700

Michael S. Dukakis
Governor

Philip W. Johnston
Secretary

Deborah Prothrow-Stith, M.D.
Commissioner

DEFIBRILLATOR USE & MAINTENANCE INVESTIGATION IN MASSACHUSETTS HOSPITALS AND AMBULANCE SERVICES

Overview of Study

The U.S. Food and Drug Administration (FDA) and the Massachusetts Department of Public Health (MDPH) collaborated on a survey of defibrillation equipment to determine the types of problems defibrillator equipment have been displaying. The FDA's Center for Devices and Radiological Health was interested in an assessment of defibrillator equipment and user related practices due to the high level of adverse incidents of defibrillators received through the Medical Device Reporting (MDR) System.

Survey Protocol

The survey included site visits to 30 hospitals and paramedic ambulance services in each of the six EMS regions throughout Massachusetts. The survey protocol covered general facility/ service information on preventative maintenance and continuing education, interview of staff regarding unit testing procedures and problems experienced with units, and a test of the accuracy of energy delivered and other selected parameters using a defibrillator analyzer (Dynatech Nevada, Model 3100B).

Summary of Findings

A total of 97 defibrillator units were tested and 76 device users (nurses and paramedics) interviewed. The unit test identified a 19% failure rate with respect to performance to specification, 67% of these failures resulted from battery related problems. Similarly, the most frequent reported problems encountered by users were battery related.

Next Steps

The findings will help clarify the reasons for the high level of MDR reports and assist the FDA in developing a course of action to solve the problems. The findings will also guide the MDPH in developing appropriate standards for the overall safety and efficacy of the units in hospitals and ambulance services. These combined efforts will reduce the frequency of injuries and deaths associated with defibrillators.

A defibrillator is probably more responsible for the decrease in sudden cardiac deaths than any other device or drug over the past 30 years. Unfortunately, many of us have come to take the defibrillator for granted and this helper is not always fully capable of performing its task.

In the past 15 years, much has been written and said about the care, training, repair and use of defibrillators. But with the introduction of more technology our overall conscious concern about defibrillators has decreased. It is this decrease in consciousness that this meeting is trying to address.

In the handout are various pieces of information that may help you in assuring that your defibrillator is always ready to serve your patients.

TESTING OF THE UNITS

When we first started a program of testing defibrillators each was done on a monthly basis. A very detailed test was performed, taking approximately 45 minutes, and after several years a review was done to look at what was accomplished. Basically, very little was ever found wrong and a change was made to test every three months. Again, after several years and many more defibs, it was determined that semi-annual made both economic and risk management sense.

TEST METHODS

There are many test methods for defibrillators as there are people servicing defibrillators. In this handout are two sample test procedures. Which is best for you is difficult to say but the simplest method that covers your needs is the best. Basically, you have to test the following:

Output
Sync
Charge/Discharge
Batteries

Page A through G covers two test methods

A user can check the defibrillator easily by doing only charge/discharge and battery test. This takes only about 45 seconds if the unit is properly functioning. If it fails these two tests a repair call should be immediately placed.

TESTING REQUIREMENT/FREQUENCY

Basically, this is a wide open area. There are no codes (laws) making specific requirements, but there are numerous guidelines.· The two most concerning hospitals are shown in Pages H through L. Both are from the JCAHO. PL-9 is what is required for the BMET and the service people and SP-5 if for nursing in an ICU.

Jim and Ken have gone over the scope of the study and the results. What was found is consitent from user to user. on Page M is an eleven month listing of problems with defibrillators at NEMC. This listing shows 63 trouble calls from 87 defibrillators in use. If you look at the problems reported, they are the same as previously reported. Based on this small sample you can expect to have a defib needing repairs every 12.5 months. The ideal is to find the problem through testing before a failure occurs in a code situation.

FAILURE REPORTING

If you find a problem, don't assume that someone else reported it to Biomedical or vendor; repair and tag the unit as not operable. If you feel the problem is due to a design fault or you have seen it often, please consider filing with ECRI or the FDA, Page N, O and P are the forms for filing. On Page Q is a report based on the FDA filings. When you do file a report you do get results, you will be contacted by the manufacturer and the FDA.

LIFE EXPECTANCY OF EQUIPMENT

While reviewing the survey data, it was surprising the age of many units seen. All defibrillators manufactured after 1974 show delivered energy, not stored energy on the charge selector. On Page R is a method of determining the life expectancy of a device. This may help you in determining when a unit should be replaced.

REPAIR PARTS

Batteries, cables and paper can be purchased from other sources than the maufacturer. The savings can be significant.

BATTERIES

Alexander Batteries	(800) 221-0019
Access Battery	(800) 526-1020

CABLES

3M	(800) 336-7657	Dick Bowman
Medtronic/Andover Medical	(800) 527-2462	Steve Craig

PAPER

Grapfic Control	(800) 828-1000

P. M. DATA SHEET

H0517 (3-77)

P.M. Schedule........MAJOR __________
........MINOR __________
Other Tests........................ __________

Manufacturer __________
Equipment Type DEFIBRILLATOR ; MONITO
Model __________
Serial __________
Control __________
Location __________

TEST #	TEST	DATE: TESTER:			DATE: TESTER:			DATE: TESTER:			DATE TESTER		
	CLEAN EXTERIOR												
	POWER CORD & PLUG												
	ECG CABLE												
	CONTROLS / CONNECTOR												
	PADDLES												
	OPERATIONAL TESTS												
	QRS INDICATOR												
	POWER LIGHT												
	CHARGE LIGHT												
	BATTERY INDICATOR												
	SYNC LIGHT												
	RECORDER												
	HEART RATE												
	DEFIB OUTPUT												
	20												
	50												
	200												
	360												
	EST												
	GRD RESISTANCE												
	LEAKAGE	OFF	ON	PAD	OFF	ON	PAD	OFF	ON	PAD	OFF	ON	PAD
	GROUND												
	NO GROUND												
	REV. POLARITY												

COMMENTS ____________________

SYMBOL KEY
OK = test or function within acceptable limits.
✓ = procedure of test performed.
R = repair work performed, refer to Equipment Repair History.
A = adjustment made.

Inspection and Preventive Maintenance Procedure:

Defibrillators

Procedure/Checklist No. 407-484 (April 1984)

Defibrillators [11-132]
Defibrillators, Battery-Powered [11-134]
Defibrillators, Line-Powered [11-137]

COMMONLY USED IN: Coronary and special care areas, emergency room, operating room, resuscitation carts, and stationed throughout the hospital in patient care areas. Defibrillators are also used in emergency medical vehicles.
SCOPE: This procedure covers battery- and line-powered defibrillators used with external and internal paddles. Use Defibrillator/Monitor Procedure No. 408 for units that include both defibrillation and monitoring functions. This procedure is not applicable to AC-output units; these older units are outmoded and should be replaced with a DC-output unit.

TYPE	INTERVAL	TIME REQUIRED
Major	6 months	__.__ hours
Minor	6 months	__.__ hours

In addition to periodic inspection, clinical staff should perform daily visual inspection and ensure that battery-powered units are charged.

Defibrillators are critical resuscitation instruments. The failure of a defibrillator to perform effectively may result in the death of a patient undergoing resuscitation, or cause further cardiac damage or death in a patient undergoing elective cardioversion or emergency cardioversion of a life-threatening arrhythmia.

Failure to successfully defibrillate a patient may occur for a number of reasons, including inadequate pre-defibrillation cardiopulmonary resuscitation (CPR) technique or operator error (*e.g.*, poor paddle application). Older defibrillators with manual *Synchronize/Emergency* switches would often be left in the synchronization mode, and thus would not discharge when used for emergency ventricular fibrillation. [Most units now available automatically turn on in the defibrillation mode and must be manually switched to the synchronization mode to minimize this problem.]

Depleted or defective batteries are the most common cause of failure in battery-powered units; for this reason, we generally recommend purchase of line-powered defibrillators, unless portability or use away from a line-power source is required. There is no time to troubleshoot or correct even minor difficulties during emergencies, since every minute of delay dramatically decreases the probability of a successful resuscitation attempt.

Citations from *HEALTH DEVICES*

Defibrillator paddles [Hazard] 1:22; 1971 Apr.
Defibrillator paddles [Update] 1:37; 1971 May.
Burdick defibrillator [Hazard] 1:42-43; 1971 May.
AC versus DC defibrillators 1:105, passim; 1971 Aug.
Inspection of defibrillators 1:109-113; 1971 Aug.
DC defibrillator inspection form 1:111-112; 1971 Aug.
Hewlett-Packard defibrillator paddles [Hazard] 1:114-115; 1971 Aug.
Cambridge AC defibrillator [Update] 1:163; 1971 Oct.
Electrodyne Model D-84M defibrillator [Hazard] 1:164; 1971 Oct.
Electronics for Medicine Model SDD defibrillator [Hazard] 1:167; 1971 Oct.
Hewlett-Packard defibrillator paddles [Update] 1:189; 1971 Nov-1972 Apr.
Hewlett-Packard & Sanborn defibrillators [Hazard] 1:239; 1972 Jun.
Mennen-Greatbatch defibrillator paddles [Update] 1:243; 1972 Jun.
American Optical defibrillators [Hazard] 2:27; 1972 Nov.
Line-operated synchronized defibrillators [Evaluation] 2:117-129; 1973 Mar.
Testing defibrillators 2:124; 1973 Mar.
Gould defibrillators [Hazard] 2:250; 1973 Aug.
Travenol Life-Lite defibrillators [Hazard] 2:250; 1973 Aug.
Physio-Control Lifepak 911 defibrillator 3:158; 1974 Apr.
Gould and Travenol defibrillators [Update] 3:182; 1974 May.
Internal defibrillator paddles [Hazard] 4:97-98; 1975 Feb.
American Optical defibrillator paddles [Hazard] 5:122-123; 1976 Mar.
Defibrillator testing: Too much of a good thing 5:192; 1976 Jun.
Ipco/Pantridge battery-powered defibrillator [Evaluation] 5:199-204; 1976 Jul.
Burdick defibrillator paddles 6:27; 1976 Nov.
Defibrillating on a water mattress [Consultant's Corner] 6:122; 1977 Mar.
Maximum required defibrillator energy [Consultant's Corner] 6:178; 1977 May.
Misuse of B-D Electrodyne defibrillator paddle connector [Hazard] 7:116; 1978 Feb.
More misuse of defibrillator paddle connectors [Hazard] 7:261; 1978 Aug.
Defibrillators [Inspection Checklist] 8:83; 1979 Feb.
Datascope Model 692 defibrillator paddles [Hazard] 10:171-172; 1981 Apr-May.
Electronics for Medicine/Honeywell internal defibrillator paddles [Hazard] 11:41; 1981 Nov.
Datamedix 450 Series internal defibrillator paddles [Hazard] 12:103; 1983 Feb.

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Daily checks of defibrillators [Consultant's Corner] 12:120-121; 1983 Mar.

Replacement battery packs for Lifepak 6 defibrillator/monitors [Hazard] 12:178-179; 1983 May.

Rupture of Lifepak battery pack during recharging [Hazard] 12:208; 1983 Jun.

Line-powered defibrillators [Evaluation] 12:291-314; 1983 Oct.

Hewlett-Packard 78660 and 78670 Series defibrillators [User Experience Network] 13:68; 1983 Dec-1984 Jan.

Test apparatus and supplies

- Defibrillator analyzer
- Ohmmeter with good resolution in the vicinity of 0.1 ohm for measuring grounding resistance. This may be part of another instrument.
- Leakage current meter or electrical safety analyzer
- Stopwatch
- Isolation test supply. This feature is included in some electrical safety test instruments.
- ECG simulator

Special precautions

THE HIGH VOLTAGE PRESENT ON DEFIBRILLATOR PADDLES DURING DISCHARGE IS EXTREMELY DANGEROUS AND POSSIBLY LETHAL. Never perform testing alone. A second person must be present to summon help and/or apply CPR in the event of an emergency. Confirm that the defibrillator is DISARMED (not charged) and preferably OFF before you hold or contact the conductive electrode portion of the paddles.

A defibrillator must be available in the event of an emergency during the inspection. Thus, either perform the inspection in the vicinity of the unit's normal storage location or ensure that a similar unit, with which the clinical staff is familiar, is available as a substitute.

Battery depletion may occur as a result of the inspection testing of battery-powered units. Ensure that a replacement unit or a fully charged battery is available before you begin testing. Do not test all battery-powered units in an area at the same time, since this will leave the staff inadequately equipped to handle emergencies until the batteries recharge.

Procedure

Before beginning the inspection, carefully read this procedure and the manufacturer's instruction and service manuals to understand how the equipment is to be operated and the significance of each control and indicator. Defibrillator energies may be specified in either watt-seconds or joules; these are equivalent units (*i.e.*, 1 watt-second = 1 joule).

1. Qualitative tests

1.1 CHASSIS/HOUSING. Examine the exterior of the unit for cleanliness and general physical condition. Be sure that plastic housings are intact, that all assembly hardware is present and tight, and that there are no signs of spilled liquids or other serious abuse.

1.2 MOUNT. If the device is mounted on a stand or cart, examine the condition of the mount. If it is attached to a wall or rests on a shelf, check the security of this attachment.

1.3 CASTERS/BRAKES. Check the condition of cart casters. Look for accumulations of lint and thread around the casters, and be sure that they turn and swivel, as appropriate. Check the operation of brakes and swivel locks; if the cart is so equipped. Conductivity checks, where appropriate, are usually done more efficiently as part of a check of all equipment and furniture of an area.

1.4 AC PLUG. Examine the AC power plug for damage. Attempt to wiggle the blades to determine that they are secure. Shake the plug and listen for rattles that could indicate loose screws. If any damage is suspected, open the plug and inspect it.

If the device is mounted on a cart that has electrical receptacles for additional equipment, insert an AC plug into each and check that it is held firmly. If devices are plugged and unplugged often, consider a full inspection of the receptacles.

1.5 LINE CORD. Inspect the cord for signs of damage. If damaged, replace the entire cord or, if the damage is near one end, cut out the defective portion. Be sure to wire a new power cord or plug with the same polarity as the old one. Check line cords of battery chargers.

1.6 STRAIN RELIEFS. Examine the strain reliefs at both ends of the line cord. Check that they hold the cord securely.

.1.7 CIRCUIT BREAKER/FUSE. If the device has a circuit breaker, check that it operates freely. If the device is protected by an external fuse, check its value and type against that marked on the chassis, and ensure that a spare is provided.

1.9 CABLES. Inspect paddle and synchronizer cables and their strain reliefs for general condition. Examine cables carefully to detect breaks in the insulation and to ensure that they are gripped securely in the connectors at each end to prevent rotation or other strain.

1.10 FITTINGS/CONNECTORS. Examine all cable connectors for general condition.

1.11 PADDLES. Special paddles (*e.g.*, pediatric, internal) should be available if appropriate for the area of use. Examine paddles for physical condition and cleanliness. The presence of dried electrode gel, physiologic fluids or debris on the surface of the paddles should be brought to the attention of the clinical personnel responsible for the instrument. Dirty electrodes prevent good electrical contact and often cause burns. Electrode gel or other debris on the insulating portion of the paddle can shock the operator. Clean the paddles, electrode surfaces, and handle seams, and make sure they are completely dry before proceeding with any testing.

1.13 CONTROLS/SWITCHES. Examine all controls and switches for physical condition, secure mounting, and correct motion. Where a control should operate against fixed-limit stops (*e.g.*, output control), check for proper alignment, as well as positive stopping. During the course of the inspection, check that each control and switch performs its proper function. If the defibrillator is used for emergency purposes, all controls should be kept in positions appropriate for such use. Specifically, on older units equipped with a synchronizer, the mode selection switch must always be left in the "Defibrillation" position, not in the "Sychronization" position.

If the unit has redundant control functions (*e.g.*, a charge button on the front panel and on a paddle), ensure that both controls function properly. Verify that the unit will not discharge when just one paddle discharge button is actuated; both must be pressed simultaneously. A front panel discharge button should control only internal paddles, and should not cause discharge when external paddles are connected.

1.17 BATTERY/CHARGER. Verify that the charger of battery-operated unit is plugged into a live AC outlet and that the charger is attached to the defibrillator (*e.g.*, charger cable is attached, unit is firmly seated into charging stand or mount, instrument end of line cord is attached and charging light is on). Inform clinical personnel of any deficiencies or improper use.

Some batteries require periodic deep discharges and recharging in order to maintain maximum capacity. If this is recommended by the manufacturer, verify that clinical personnel are performing this function on schedule.

1.18 INDICATORS/DISPLAYS. During the course of the inspection, confirm the operation of all lamps, indicators, meters, gauges, and visual displays on the unit and charger, if so equipped. Be sure that all segments of a digital display function.

1.21 AUDIBLE SIGNALS. Operate the device to activate any audible signals (*e.g.*, charge tone). Confirm appropriate volume, as well as the operation of a volume control.

1.22 LABELING. Check that all necessary placards, labels, conversion charts, and instruction cards are present and legible.

1.23 ACCESSORIES. *Gel or pads.* Verify that electrode gel, saline pads or defibrillator pads are stored with the unit, and confirm that it is indeed electrode gel, not skin lubricant. Notify appropriate clinical personnel if these items are missing.

1.24 INTERNAL DISCHARGE OF STORED ENERGY. To protect personnel from accidental shock, it should be possible to discharge the stored energy safely in the event that the physician decides not to use the defibrillator after it has been charged. In some units, there is a front-panel button for this purpose. Others release the stored energy rapidly when the power is turned off. Consult the operator's manual for the method used for the defibrillator being inspected, and verify proper operation.

1.25 SYNCHRONIZER. If the unit has a synchronization mode, verify that it will not discharge while in this mode when no ECG signal is present, and that it will discharge when a simulated ECG signal is applied.

2. *Quantitative tests*

2.1 GROUNDING RESISTANCE. Using an ohmmeter, electrical safety analyzer, or multimeter with good resolution of fractional ohms, measure and record the resistance between the grounding pin of the power cord and exposed (unpainted and not anodized) metal on the chassis. We recommend a maximum of 0.5 ohm.

2.2 LEAKAGE CURRENT. Measure chassis and paddle leakage current to ground with the grounding conductor of plug-connected equipment temporarily opened, and with both correct and reversed hot-neutral wiring. Measure chassis leakage current with the unit off, on, charging, and charged, and measure paddle leakage current to ground with the unit off and on. Also measure paddle leakage current with the power cord grounding intact. DO NOT MEASURE PADDLE LEAKAGE CURRENT WITH THE UNIT CHARGED, CHARGING, OR DURING DISCHARGE. Record the maximum leakage current and the associated wiring and operating mode. Leakage current must be less than 100 μA from chassis to ground, and 50 μA from external paddles to ground. Leakage current from internal paddles should not exceed 10 μA. [The rationale for the differences in limits is that the internal paddles are in direct contact with the heart, but the external paddles are not. Note that ANSI DF2-1981, *Standard for Cardiac Defibrillator Devices*, permits 100 μA leakage current to ground for external paddles, and 50 μA for internal paddles.]

2.3 INTER-PADDLE LEAKAGE. With the unit on and connected to the AC power line, measure leakage current between the defibrillator paddles. If the unit has an ungrounded metal housing, also measure leakage from each paddle to the housing. Do not measure interpaddle leakage current with the unit charging, fully charged, or during discharge. Leakage current between external and internal paddles should be less than 50 and 10 μA, respectively.

2.4 PADDLE CONTINUITY. Use an ohmmeter to verify continuity from each paddle to the appropriate pin of the paddle connector. Check that continuity is not affected by wiggling, bending, or stretching the cable, especially near the paddle and connector. [Current may jump across a small break in the paddle lead and may not be detected during defibrillator output tests. An ohmmeter test will detect such a discontinuity before it gets worse.]

2.5 ENERGY AFTER 60 SECONDS. Deterioration of the energy storage capacitors in some defibrillators results in charge leakage after the charging circuit had been de-energized. In these units, it is possible for the available energy to decrease if the unit is not discharged at the earliest possible moment. Use the following test to identify this deficiency.

Charge the defibrillator to its maximum setting, but do not discharge it for one minute. Compare the delivered energy with that obtained when the unit is discharged immediately (as in Item 2.10) and with manufacturer specifications for charge leakage. It should not have decreased more than 15% or the amount specified by the manufacturer. [Note: Some units are designed to intentionally bleed or discharge the capacitor charge if the defibrillator is not discharged within a set time period.]

2.6 INTERNAL PADDLE ENERGY LIMIT. Defibrillator output when used with internal paddles should be limited to 50 J or less. This feature must be tested on any unit that is located where it may be used with internal paddles, or if the unit is portable and may be moved to such a location.

Connect the internal paddles, charge the unit to maximum energy, and discharge it into the defibrillator analyzer. Verify that the output is 50 J or less or no greater than the manufacturer's specification (typically about 50 J).

2.10 OUTPUT ENERGY. Measure output energy at minimum, intermediate, and maximum output energy settings. If the defibrillator is commonly used for cardioversion, a 50 J level would be satisfactory for the intermediate range.

Discharge the defibrillator into the defibrillator analyzer at each energy level in turn. Record the control setting, indicated energy (on the unit's energy meter), and delivered energy (measured by an analyzer for each discharge). At its maximum setting, the unit should be able to deliver at least 250 J, and the delivered energy should be within 4 J at low settings (below 25 J) or 15% of the set energy (and indicated energy if the unit has a meter).

All defibrillators should be calibrated in units of energy deliverable into a 50-ohm load. If this is not the case, as on older units, recalibrate and label the energy selector and meter. [On earlier units, the energy control knob and meter indicate stored energy, rather than that delivered to a 50-ohm load, and their readings will typically be 10–30% higher than the energy reading on the defibrillator analyzer.]

An unusually low output at very low control settings may indicate a break in the cables or a defective connector.

2.11 CHARGE TIME TO MAXIMUM ENERGY. In resuscitation attempts, it is not uncommon for the physician to call for multiple defibrillation shocks in rapid succession. Some cases have been reported in which the circuit breaker of a line-powered defibrillator tripped under such conditions. Battery-powered defibrillators may not have sufficient energy left in their batteries to deliver 10 shocks. These deficiencies are best discovered during periodic inspections, rather than during clinical use.

Charge the unit to its maximum energy and discharge it 10 times through the analyzer (but first verify that the analyzer load will not be damaged by repeated discharge). On the tenth cycle, record the charging time (the time it takes the meter to equilibrate or the "ready" light to come on) and the delivered energy. [To avoid excessive battery depletion, stop the test and record the number of discharges and the values measured if the charging time exceeds 30 seconds before the tenth discharge. Also stop the test if the battery condition meter indicates a weak battery or, on some defibrillators, if the internal circuitry terminates the charge early.]

The output energy should not decrease significantly from the first discharge or that recorded in Item 2.10. The time to charge to maximum energy should be 15 seconds or less.

CAUTION: Do not perform this test on all battery-operated defibrillators in an area on the same day unless provisions are made for backup units or spare charged batteries. Batteries may take considerable time to recharge, and a fully charged unit must be available for an emergency.

A significant increase in charging time compared to previous inspections can indicate low power line voltage, deterioration of the charging circuit, or deterioration of batteries in battery-powered units. This test will have to be modified slightly for some defibrillators. Units that charge at a tapering rate might introduce large errors into the measurement, since it is difficult to determine the precise moment that full charge is reached. For these units, it would be appropriate to measure the charging time to 90% of the final indicated energy. In some defibrillators, the maximum energy level is well off the meter scale. Use the time to charge to the highest meter graduation.

3. *Preventive maintenance*

3.1 CLEAN the exterior and paddles.

3.4 BATTERY REPLACEMENT. Replace the battery if any of the test procedures indicate a weak or defective battery, even after charging for 12 or more hours.

Some users have also reported that periodic prophylactic battery replacement either annually or every two years increases reliability and decreases service calls. In such a case, mark the date of the battery replacement on the battery or unit and check it during each inspection. Perform inspection after battery replacement and a suitable charge period.

4. *Acceptance tests*

4.1 PADDLE ISOLATION. This test will confirm the isolation of internal paddles on units so equipped.

Verify that the defibrillator chassis is grounded via the line cord or charger; if not, use a ground wire connected to the metal chassis. Connect an isolation test supply (see the section on Electrical Safety) to each internal paddle and measure the current flow. The Instrutek Model ITS isolation test supply is useful for obtaining the appropriate voltage and resistance without exposing the operator directly to the power line. Alternatively, some electrical safety test instruments include an isolation test that is appropriate for this measurement.

The measured current should not exceed 20 μA (10 μA if the paddle cable is not used and the current is measured directly to the cable connector on the defibrillator). If the measured current far exceeds these limits, the isolation may have failed. This is a serious condition, and must be repaired before the unit is accepted or returned to service.

Isolated input is required only on devices intended for internal defibrillation. Since only internal paddles will make direct contact with the heart, external paddle units need not be isolated. However, this test can be used on external paddles to check output relay insulation.

4.2 SYNCHRONIZER OPERATION. The thoroughness of this test will depend upon the sophistication of the hospital and the availability of test equipment. Use an ECG signal from an ECG simulator to trigger the synchronizer to discharge the defibrillator into a dummy load (*e.g.*, a defibrillator analyzer). Set the defibrillator to deliver low output energy (50 J or less). Confirm that the unit does discharge with a signal applied, but will not discharge when the discharge buttons are depressed with the ECG simulator off. Confirm that the synchronizer marker or other indicator is functioning properly.

A dual-channel oscilloscope can be used to note the time delay betwee a QRS pulse (from an ECG simulator) and the defibrillator pulse (from a defibrillator analyzer). Use the ECG signal to trigger the oscilloscope's sweep. Some defibrillator analyzers have synchronizer test functions.

With an ECG amplitude sufficient to activate the marker or indicator, the defibrillator should discharge in 30 msec or less following a QRS after the discharge buttons are depressed. Most units will trigger on the first QRS after depressing the buttons, although some units are designed to delay until the second or third QRS to avoid unintentional discharges.

4.3 INTERNAL PADDLE ENERGY LIMIT. During acceptance testing, perform Item 2.6 on all units equipped with this feature, regardless of the intended device location.

Before returning to use

Return the energy select control to its normal setting.

Before connecting the charger on battery-powered units, check the battery condition meter indicator to verify that there is an adequate battery charge. If there is not, or if doubt exists, replace the unit with another defibrillator and allow the unit just inspected to charge in an out-of-the-way location (*i.e.*, where it will not be taken for use by clinical personnel). Otherwise, connect battery-powered units to the charger, plug the charger into a wall outlet, and verify that the charging light is on.

Units with Synchronize/Emergency switches should be in the Emergency mode.

DEFIBRILLATORS

Checklist No. 407-484

	Inspection	
	Major	Minor
1. QUALITATIVE TESTS		
1.1 CHASSIS/HOUSING	X	X
1.2 MOUNT	X	X
1.3 CASTERS/BRAKES	X	X
1.4 AC PLUG/RECEPTACLES	X	X
1.5 LINE CORD	X	X
1.6 STRAIN RELIEFS	X	X
1.7 CIRCUIT BREAKER/FUSE	X	X
1.8		
1.9 CABLES	X	X
1.10 FITTINGS/CONNECTORS	X	X
1.11 PADDLES	X	X
1.12		
1.13 CONTROLS/SWITCHES	X	X
1.14		
1.15		
1.16		
1.17 BATTERY/CHARGER	X	X
1.18 INDICATORS/DISPLAYS	X	X
1.19		
1.20		
1.21 AUDIBLE SIGNALS	X	X
1.22 LABELING	X	X
1.23 ACCESSORIES [Gel or pads]	X	X
1.24 INTERNAL DISCHARGE OF STORED ENERGY	X	X
1.25 SYNCHRONIZER	X	
2. QUANTITATIVE TESTS		
2.1 GROUNDING RESISTANCE [<0.5 ohm]	X	X
2.2 LEAKAGE CURRENT [<100 μA chassis, <10 μA leads]	X	
2.3 INTERPADDLE LEAKAGE [10 μA]	X	
2.4 PADDLE CONTINUITY	X	
2.5 ENERGY AFTER 60 SEC [<15% loss]	X	
2.6 INTERNAL PADDLE ENERGY LIMIT [<50 J]	X	
2.7		
2.8		
2.9		
2.10 OUTPUT ENERGY [>250 joules, or 15% of set point]	X	X
2.11 CHARGE TIME TO MAXIMUM ENERGY [10th charge <15 sec.]*	X	X
2.12		

*Battery powered units only.

	Major	Minor
3. PREVENTIVE MAINTENANCE		
3.1 CLEAN exterior, paddles	X	X
3.2		
3.3		
3.4 BATTERY: Replace as needed	X	X

4. ACCEPTANCE TESTS

4.1 PADDLE ISOLATION

4.2 SYNCHRONIZER OPERATION

4.3 INTERNAL PADDLE ENERGY LIMIT

TEST APPARATUS AND SUPPLIES

- Defibrillator analyzer
- Ohmmeter
- Stopwatch
- Leakage current meter
- Isolation test supply
- ECG simulator

NOTES

		Circle One
PL.8.3	There are reliable methods for detecting partial or complete failure of vital segments of any communication system and for ensuring that the system is rapidly returned to operation.*	1 2 3 4 5 NA
	PL.8.3.1 In those parts of the communication system where an equipment failure can have life-threatening consequences, the hospital has procedures for implementing an alternative means of communication.*	1 2 3 4 5 NA
PL.8.4	A reliable call mechanism is provided in locations where patients may be left unattended.*	1 2 3 4 5 NA
	PL.8.4.1 Such locations include patient rooms, toilet and bathing areas, and designated high-risk treatment areas where individuals may need to summon assistance.	1 2 3 4 5 NA
PL.8.5	Segments of any communication system used for emergency alerts are designed to override any other signals using the same equipment.*	1 2 3 4 5 NA
PL.8.6	Individuals are trained in the use of the communication systems.*	1 2 3 4 5 NA
	PL.8.6.1 It is recommended that training programs relate specifically to the individuals' prescribed duties.	1 2 3 4 5 NA

Standard: Patient Care Equipment

PL.9	Where appropriate, the hospital has a program designed to assure that patient care equipment, whether electrically or nonelectrically powered, performs properly and safely and that individuals are trained to operate the equipment they use in the performance of prescribed duties.	1 2 3 4 5 NA

Required Characteristics

PL.9.1	There is a list of all powered equipment—regardless of ownership—currently used in the hospital for the diagnosis, treatment, or monitoring of patients.*	1 2 3 4 5 NA
PL.9.2	There are required safety and performance testing procedures for all the powered equipment listed.*	1 2 3 4 5 NA
PL.9.3	Records that document acceptable performance against stated procedures are maintained.*	1 2 3 4 5 NA
PL.9.4	All equipment listed is tested prior to initial use and at intervals not to exceed six months, unless a different interval is justified by previous experience and is approved by the safety committee.*	1 2 3 4 5 NA
PL.9.5	There is documentation that the status of equipment used within a department, service, or area is reported to the appropriate personnel.*	1 2 3 4 5 NA
PL.9.6	The program includes a procedure for identifying and correcting equipment malfunctions.*	1 2 3 4 5 NA
PL.9.7	There are user/operator instructions for every item identified in the patient care equipment list.*	1 2 3 4 5 NA

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*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

Circle One

PL.9.7.1 Consideration is given to providing abbreviated user operating information and user trouble-shooting information for immediate reference.* 1 2 3 4 5 NA

PL.9.8 Individuals are trained to operate the equipment they use in the performance of prescribed duties.* 1 2 3 4 5 NA

Standard: Electrically Powered Equipment

PL.10 The hospital has a program designed to assure that non-patient-care, electrically powered, line-operated equipment is electrically safe. 1 2 3 4 5 NA

Required Characteristics

PL.10.1 There is a policy that identifies types of non-patient-care equipment that may pose an electrical hazard during intended use.* 1 2 3 4 5 NA

PL.10.1.1 In the development of the policy, consideration is given to the environment of use, maintenance, design safety features, and type of service the equipment provides.

PL.10.2 Non-patient-care equipment identified by the policy is inspected prior to initial use and at intervals to determine electrical safety.* 1 2 3 4 5 NA

PL.10.2.1 The intervals are determined by the requirements of the equipment.

PL.10.3 Documentation of inspections and appropriate corrective actions is maintained.* 1 2 3 4 5 NA

PL.10.4 The safety committee develops and implements policies for the use and control of personal electrical equipment. 1 2 3 4 5 NA

Standard: Electrical Distribution

PL.11 The hospital has an electrical distribution system that is designed, installed, operated, and maintained in a manner designed to provide electrical power for all required operations. 1 2 3 4 5 NA

Required Characteristics

PL.11.1 There is a program of preventive maintenance and periodic inspection designed to assure that the electrical distribution system operates safely and reliably.* 1 2 3 4 5 NA

PL.11.1.1 Inspections and corrective actions are documented.* 1 2 3 4 5 NA

PL.11.2 In identifying components of the electrical distribution system to be included in the program, consideration is given to the reliability of receptacles, electrical feeds, and transformers. 1 2 3 4 5 NA

PL.11.3 There are written procedures that specify the action to be taken during a failure of essential electrical systems or equipment or sources of electrical supply.* 1 2 3 4 5 NA

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*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

Standard		Circle One
SP.5	Special care units are designed and equipped to facilitate the safe and effective care of patients.*	1 2 3 4 5 NA
Required Characteristics		
SP.5.1	Each special care unit is organized as a physically and functionally distinct entity within the hospital.	1 2 3 4 5 NA
	SP.5.1.1 Access is controlled in order to regulate traffic, including visitors, and in the interest of infection control.	1 2 3 4 5 NA
SP.5.2	An effective means of isolation is provided for patients suffering from communicable or infectious disease, for patients requiring protective isolation, and for disoriented or emotionally disturbed patients who require the services of the unit until placement elsewhere becomes possible.*	1 2 3 4 5 NA
	SP.5.2.1 Separate isolation rooms are recommended when feasible.	1 2 3 4 5 NA
	SP.5.2.2 An effective means of separating children from adults is provided whenever possible.	1 2 3 4 5 NA
SP.5.3	Direct or indirect visual observation by unit staff of all patients is possible from one or more vantage points.	1 2 3 4 5 NA
SP.5.4	Patient care areas are separate from other areas within the unit, such as storage space and lounges for personnel, medical staff, and visitors.	1 2 3 4 5 NA
SP.5.5	The floor space allocated to each bed is sufficient to accommodate the equipment and personnel necessary to meet anticipated contingencies.	1 2 3 4 5 NA
SP.5.6	A direct intercommunication/alarm system is provided between the nurses' station and the patient's bedside, with connections to treatment, work, lounge, or other areas from which additional personnel may be summoned.	1 2 3 4 5 NA
	SP.5.6.1 The patient/nurse call system is adapted for use by the patient.	1 2 3 4 5 NA
SP.5.7	Beds are adjustable to positions required by the patient, are easily movable, and have a locking or stabilizing mechanism to attain a secure, stationary position.	1 2 3 4 5 NA
	SP.5.7.1 Headboards, when present, are removable or adjustable to permit ready access to the patient's head, as well as immediate use in cardiac compression procedures.	1 2 3 4 5 NA
SP.5.8	Wall installation of equipment is recommended to facilitate the placement of portable equipment, personnel movement, and cleaning procedures.	1 2 3 4 5 NA
SP.5.9	The equipment provided is suitable for the size of the patient being treated.	1 2 3 4 5 NA

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*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

		Circle One
SP.5.10	When not provided in the unit, at least the following are readily available in the hospital for use within each special care unit:*	
	SP.5.10.1 Oxygen and compressed air and the means of administration;	1 2 3 4 5 NA
	SP.5.10.2 Mechanical ventilatory assistance equipment, including airways, manual breathing bags, and ventilators/respirators;	1 2 3 4 5 NA
	SP.5.10.3 Cardiac defibrillator with synchronization capability;	1 2 3 4 5 NA
	SP.5.10.4 Respiratory and cardiac monitoring equipment;	1 2 3 4 5 NA
	SP.5.10.5 Thoracentesis and closed thoracostomy sets;	1 2 3 4 5 NA
	SP.5.10.6 Tracheostomy set;	1 2 3 4 5 NA
	SP.5.10.7 Tourniquets;	1 2 3 4 5 NA
	SP.5.10.8 Vascular cutdown sets;	1 2 3 4 5 NA
	SP.5.10.9 Infusion pumps;	1 2 3 4 5 NA
	SP.5.10.10 Laryngoscopes and endotracheal tubes;	1 2 3 4 5 NA
	SP.5.10.11 Tracheobronchial and gastric suction equipment;	1 2 3 4 5 NA
	SP.5.10.12 Portable x-ray; and	1 2 3 4 5 NA
	SP.5.10.13 Patient weighing device for bed patients.	1 2 3 4 5 NA
SP.5.11	Life-support equipment brought from other hospital departments/services as replacement items are checked for operational readiness and safety prior to use.*	1 2 3 4 5 NA
	SP.5.11.1 An adequate number of electrical outlets for each patient bed are available.	1 2 3 4 5 NA
SP.5.12	An emergency cart within the unit contains appropriate drugs and equipment, as determined by the medical staff.	1 2 3 4 5 NA
	SP.5.12.1 The emergency cart is checked at least on every shift and after each use by an appropriate, designated member of the hospital staff to assure that all items required for immediate patient care are in place in the cart and in usable condition.	1 2 3 4 5 NA
	SP.5.12.1.1 Any system that assures continued integrity of the cart contents between periods of use is acceptable.	1 2 3 4 5 NA
	SP.5.12.2 Uniformity of drug and equipment display is recommended to facilitate rapid implementation of emergency care.	1 2 3 4 5 NA
SP.5.13	Clinical laboratory services are readily available 24 hours a day.*	1 2 3 4 5 NA
	SP.5.13.1 Such laboratory services have the capability of performing all necessary laboratory tests, with timely reporting of results, including chemistries, blood gas analysis, pH levels, electrolyte determinations, and serum and urine osmolality.*	1 2 3 4 5 NA
	SP.5.13.1.1 When warranted by the size of the patients, microtechniques are used.	1 2 3 4 5 NA
	SP.5.13.1.2 Microbiology services are readily available.*	1 2 3 4 5 NA

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*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

Circle One

SP.5.14 The unit or hospital assures that there is an adequate supply of blood to meet the needs of patients at all times.* 1 2 3 4 5 NA

SP.5.15 When hemodialysis is not provided within the hospital, it is available to the patient as needed. 1 2 3 4 5 NA

SP.5.16 Diagnostic radiological services are readily available 24 hours a day.* 1 2 3 4 5 NA

SP.5.17 Refrigerated storage is provided for biologicals and all other supplies requiring such storage within the special care unit. 1 2 3 4 5 NA

SP.5.17.1 Supplies that meet special or supplementary dietary requirements are stored separately from biologicals. 1 2 3 4 5 NA

SP.5.18 Special precautions, including those related to electrical and device safety, are taken when the care of a patient requires the use of any type of electrically operated device.* 1 2 3 4 5 NA

SP.5.18.1 All special care unit personnel involved in direct patient care are informed when specific patients have particular sensitivity to electrical current.* 1 2 3 4 5 NA

SP.5.19 Pertinent findings from the preventive maintenance and infection control programs and the analysis of safety practices are made available to the director and to the nurse supervisor or head nurse of the special care unit. 1 2 3 4 5 NA

Standard

SP.6 As part of the hospital's quality assurance program, the quality and appropriateness of the patient care provided by special care units are monitored and evaluated, and identified problems are resolved.* 1 2 3 4 5 NA

Required Characteristics

SP.6.1 Special care units have a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of patient care and for resolving identified problems.* 1 2 3 4 5 NA

SP.6.1.1 The physician director of a specific-purpose special care unit is responsible for assuring that the process is implemented.* 1 2 3 4 5 NA

SP.6.1.2 In a multipurpose special care unit, a multidisciplinary team is responsible for assuring that the process is implemented.* 1 2 3 4 5 NA

SP.6.2 The quality and appropriateness of patient care are monitored and evaluated in all major clinical functions of special care units.* 1 2 3 4 5 NA

SP.6.2.1 Such monitoring and evaluation are accomplished through the following means:

SP.6.2.1.1 Routine collection in the special care unit, or through the hospital's quality assurance program, of information about important aspects of care;* and 1 2 3 4 5 NA

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*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page ix.

Record#	SVC_DATE	LBR_COST	PART_COST	PARTS	COMMENTS	PROBLEM
428	04/04/87	90.00	0.00		GOT ONE FROM P.C.E.	LIFE PACK-6 PWR.SW. BROKEN
439	04/06/87	50.00	150.00	BATT'S. & MISC	REPAIR POWER SWITCH	REPAIR LIFEPAK 6
494	04/08/87	60.00	135.00	1 DEFIB + 1 MON.BATT		CHECK LIFEPAK 7 BATTERIES AND SWITCH
525	04/09/87	70.00	0.00	LISTED		REPAIR DEFIBRILLATOR
535	04/09/87	30.00	60.00	ACCESS BATTERY	NEW DEFIB BATTERY	DEFIB BATTERY WEAK
564	04/10/87	50.00	60.00	1 DEFIB. BATTERY		PM AND REPLACE DEFIB. BATTERY
582	04/13/87	40.00	0.00			CHECK BUTTON ON PORTABLE DEFIB
771	04/23/87	30.00	0.00	1 DEFIB. BATTERY	1 HEYCO 1BUTTONCOVER	REPAIR AND PM LIFEPAK 6S
799	04/24/87	40.00	130.00	2 EA BATERIES		REPLACE BATTERIES
809	04/24/87	40.00	130.00	2 EA BATTERIES		REPLACE BATERIES IN DEFIB
873	04/28/87	90.00	135.00	1MON.BAT.1DEFIB.BAT.		LIFEPAK 6S PM AND BATTERY REPLACEMENT
907	04/30/87	90.00	63.75	1 DEFIB.BAT. 1PLUG		REPLACE BATTERY IN LIFEPAK 7 DEFIB.
916	04/30/87	100.00	135.00	1MON.1DEF.BATT.RELAY	LORAINE, BI 6	REPAIR AND PM LIFEPAK 6S
947	05/04/87	40.00	130.00	2 EA BATTERIES		REPLACE BATTERIES IN DEFIB
966	05/04/87	50.00	135.00	1MON.BAT.1DEFIB.BAT		REPLACE BATTERIES AND PM LIFEPAK 6S
969	05/04/87	50.00	135.00	1MON.BAT.1DEF.BAT.		REPLACE BATTERIES AND PM LIFEPAK 6S
990	05/05/87	60.00	60.00	1 DEFIB. BATTERY		REPLACE BATTERY AND PM LIFEPAK 7
1018	05/06/87	40.00	135.00	BATTERY		REPLACE DEFIB BATT
1020	05/06/87	200.00	7.57	MISC.	DESIGN INTERFACE	MODIFY LP-7
1231	05/19/87	200.00	11.35	LISTED		CHECK OUT DEFIB — CHARGE LIGHT+SWITC
1357	05/26/87	60.00	135.00	1MONITOR1DEFIBBATT.		REPLACE BATTERIES AND PM LIFEPAK
1361	05/26/87	30.00	0.00			CHECK DEFIB
1521	06/04/87	160.00	46.00			REPAIR CASE ON DEFIB
1529	06/04/87	20.00	45.00	1 3M #N3C68 CABLE		REPLACE PT CABLE ON PORTABLE MONITOR
1827	06/19/87	50.00	45.00	CABLE N3C68		REPAIR TWISTED CASE ON DEFIB/MONITOR
2058	07/02/87	40.00	135.00	1 MONITOR,1 DEFIB.	BATTERIES 1 382BULB	REPAIR AND PM LIFEPAK 6
2059	07/02/87	40.00	135.00	1MONITOR,1DEFIB BAT		PM LIFEPAK 7
2192	07/14/87	280.00	161.00	HV BAORD		CHECK DEFIB, NO DISPLAY
2247	07/15/87	30.00	0.00			REPAIR DEFIB — UNIT DROPED
2521	07/31/87	40.00	135.00	1MONITOR 1DEFIB BAT.	BAT.REPLACEMENT	PM DEFIBRILLATOR LIFEPAK 7
2522	07/31/87	40.00	135.00	1MONITOR1DEFIBBAT.	BATTERY REPLACEMENT	PM DEFIBRILLATOR LIFEPAK 7
2523	07/31/87	50.00	135.00	1MONITOR1DEFIB BAT.	REPLACE BATTERIES	PM DEFIBRILLATOR LIFEPAK 6
2533	07/31/87	40.00	0.00		PM	PM LIFEPAK 7
2941	08/26/87	250.00	140.00	BATTERY/IC		CHECK DEFIBRILATOR
2967	08/27/87	50.00	185.75	BATTERIES,PLUG,CABLE	REPLACE BAT.AND PM	CHECK DEFIB BATTERIES
2968	08/27/87	50.00	180.00	BATTERIES,CABLE	REPLACE BAT.AND PM	CHECK DEFIB BATTERIES
2998	08/31/87	60.00	72.50	1#800310-995COVER	REPLACE MON.COVER+PM	REPAIR AND PM LIFEPAK7
3004	08/31/87	20.00	45.00	1 CABLE 3M N3C68		REPLACE CABLE ON DEFIB
3043	09/02/87	10.00	5.75	PLUG		DEFIB PLUG
3128	09/08/87	40.00	0.00			CHECK DEFIB. REPAIR LEAD WIRE ENDS
3304	09/16/87	20.00	45.00	1 EA. P.CABL. N5C68		CHECK LIFEPAK 6 DEFIB.
3351	09/21/87	40.00	0.00		BWD 3, TERRY, 6283	CHECK DEFIBRILLATOR
3391	09/23/87	140.00	36.00	SWITCH + TRANSISTOR	SPILLED PASTE	REPAIR DEFIBRILLATOR
3461	09/28/87	37.50	0.00		TEST	CHECK DEFIBRILLATOR
3471	09/29/87	75.00	180.00	BATTERIES+CABLE	REPLACE BAT.+PM	CHECK LIFEPAK DEFIB
3617	10/07/87	100.00	37.95	RELAY	BIEWIND 3	CHECK LIFEPAK 7 TRANSFERE RELAY
3702	10/13/87	50.00	0.00			CHECK DEFIB
3899	10/26/87	50.00	275.00	CRT		CHECK LIFEPAK 7
3934	10/27/87	75.00	60.00	1 DEFIB BATT	REPLACE BATT+PM	REPAIR LIFEPAK6S
4274	11/16/87	50.00	0.00			CHECK DEFIBRILLATOR
4331	11/18/87	75.00	190.00	BATTERIES/CABLE		CHECK PORTABLE DEFIBRILLATOR
4405	11/23/87	125.00	160.00	ON WORK ORDER	REPARE CHARGER	REPAIR LIFEPAK 6
4415	11/23/87	75.00	35.00	POWER RELAY	BIEWIND 14	CHECK DEFIB
4421	11/23/87	75.00	0.00			CHECK DEFIB
4667	12/10/87	75.00	350.00	HV BOARD		CHECK PHYSIO MONITOR
4780	12/16/87	250.00	40.00	RELAY/IC/SWITCH		ON/OFF SWITCH ON DEFIB
5271	01/08/88	50.00	280.00	ADULT PADDLES		CHECK OPERATION OF DEFIBRILLATOR
5309	01/11/88	37.50	75.00	1 MONITOR BATTERY	REPLACE MONITOR BAT	CHECK LIFEPAK 7 LOW MONITOR BATTERY
5635	01/27/88	25.00	0.00		TESTED+PM	CHECK+PM LIFEPAK 7
5853	02/08/88	37.50	25.75	PLUG,FOOT BRACE		BED REPAIR
5929	02/11/88	25.00	0.00		PM	PM LIFEPAK 7
6271	03/02/88	50.00	135.00	1MONITOR 1DEFIB BAT	REPLACE BAT+PM	REPAIR+PM LIFEPAK 7
6312	03/04/88	25.00	0.50	1 TAG	INCOMING TESTS	INCOMING ON LIFEPAK 6S

User Experience Network™

Problem Reporting Form

Use this form to report a problem or hazard related to the use of medical devices or equipment. Telephone or telex reports are acceptable. Information may also be sent via telecopier with CCITT Group I, II, or III capabilities by calling (215) 834-1275.

Your personal and institutional identities will not be revealed in any way without your permission.

Your Name: ______________________ **Date:** __________
Please type or write legibly

Title: ______________________

Department: ______________________

Institution: ______________________

Address: ______________________

____

Phone: __________ **Ext.:** ______

May we identify you to the manufacturer and/or supplier of the device(s) involved? **Yes** ☐ **No** ☐

DEVICE IDENTIFICATION

Please be as specific as possible in identifying the devices involved. Please add any other information that might be helpful and omit any items that are not known or that appear irrelevant to this particular problem.

Type of Device(s) Involved: ______________________

____

Manufacturer: __________ Model: __________

Serial/Lot No.: __________ Expiration/Use Before Date: __________

How Long in Use? __________ Condition: __________

Date Last Inspected or Serviced: __________ Date Problem Occurred: __________

Will you send the affected device to ECRI for examination, if requested? **Yes** ☐ **No** ☐

Were other devices involved? **Yes** ☐ **No** ☐ If yes, please identify all other units on the reverse side, including the information listed above.

Are other units of the same model similarly affected? **Yes** ☐ **No** ☐

PROBLEM DESCRIPTION

Could (or did) the described problem result in injury? **Yes** ☐ **No** ☐ **Unknown** ☐

Please use the **reverse side of this form or separate sheets** to describe the problem or hazard in detail. Include how it was discovered, any action you took, and the response of any vendors or manufacturers. Attach copies of any related correspondence, where possible. Sketches, photographs, or copies of portions of operating manuals are often helpful in describing the problem, especially if the affected device is not available for examination at ECRI. Retain all disposable accessories possibly involved in an incident. Please do not send any device to ECRI until requested.

SIGNATURE: ______________________

Please mail completed form to ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462
(215) 825-6000 ● TWX 510-660-8023 ● Fax (215) 834-1275

This form may be reproduced without prior permission

ECRI-02-1187 Rev

ECRI
A NONPROFIT AGENCY
5200 BUTLER PIKE
PLYMOUTH MEETING, PA 19462

NEW REPORT FORM ... A PROBLEM?

Since the initial mailing of the revised Medical Device and Laboratory Product Problem Reporting Program (PRP) Form, a number of comments have been received. Many of the comments indicated that one area of the form appears to be causing confusion, namely Section 3 which lists the identity disclosure options.

The USP sends a copy of each report it receives to the Food and Drug Administration (FDA). The FDA may contact you for further information about your report or to discuss your observations. The identity disclosure options on the form then allow you to express your preference as to what *other* disclosure of your identity can be made (other than to FDA) on copies of the report that are distributed either to the product manufacturer by the USP or to third parties by the FDA in response to requests for information. Since the options are exclusive of one another, only one selection is necessary.

Review of Disclosure Options

First option: No Public Disclosure

The first selection, "No Public Disclosure", is the most limited option and provides that your name will not be released by the FDA or the USP. Although a copy of the report is sent to the manufacturer to inform him of your problem, by checking the "No Public Disclosure" option, your identity will not be included on that copy and the USP will act as your intermediary for any future correspondence with the firm.

Second option: To the Manufacturer/ Distributor

The USP sends a copy of your report to the manufacturer/distributor of the product. By selecting the second option, "To the manufacturer/ distributor", you are giving the USP express permission to include your name on this copy only. For those who have used the PRP in past years, it may be helpful to know that checking this option provides that your report will be handled as it has been over the years. By including your name on this copy you enable the manufacturer to directly discuss the problem with you. This discussion may include a request for a sample or follow up at your institution to inspect the device or perhaps inservice instruction where necessary.

Third option: To the Manufacturer/Distributor and to anyone who requests a copy of the report from the FDA

According to Federal Freedom of Information regulations, FDA records must be made uniformly available to the general public upon request. Those in the general public who may request such information could include other practitioners who are making purchase decisions, manufacturers seeking out disgruntled customers of competitors, members of the press, insurance agents, and attorneys to name a few. Checking this box allows your name to remain on any copies distributed to the general public. Depending on your perspective, this selection may or may not be desirable as it could result in many wanted or unwanted phone calls for you! The FDA will not release your name, hospital name, address, telephone number, etc. *unless you select this option.*

We hope that this brief overview will assist you in making an informed decision about your choice. If you have any questions about this procedure, please do not hesitate to call us at 800-638-6725 and our staff will be glad to assist you.

Medical Device & Laboratory Product Problem Reporting Program

Form Approved; OMB No. 0910-0143

DATE RECEIVED

ACCESS NO

1. PRODUCT IDENTIFICATION:

Name of Product and Type of Device
(include sizes or other identifying characteristics and attach labeling, if available)

Manufacturer's Name ____

Manufacturer's City, State, Zip Code ____

Is this a disposable item? YES ☐ NO ☐

Lot Number(s) and Expiration Date(s) (if applicable)

Serial Number(s)

Manufacturer's Product Number and/or Model Number

2. REPORTER INFORMATION:

Your Name ____ Today's Date ____

Title and Department ____

Facility's Name ____

Street Address ____

City ____ State ____ Zip ____ Phone ( ) ____ Ext: ____

3. PROBLEM INFORMATION:

Date event occurred ____

This event has been reported to: Manufacturer ☐ FDA ☐

Other ____

Please indicate how you want your identity publicly disclosed:

No public disclosure ☐

To the manufacturer/distributor ☐

To the manufacturer/distributor and to anyone who requests a copy of the report from the FDA ☐

If requested, will the actual product involved in the event be available for evaluation by the manufacturer or FDA? YES ☐ NO ☐

Problem noted or suspected (Describe the event in as much detail as necessary. Attach additional pages if required. Include how and where the product was used. Include other equipment or products that were involved. Sketches may be helpful in describing problem areas.)

RETURN TO
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852
Attention: Dr. Joseph G. Valentino

OR

CALL TOLL FREE ANYTIME
800-638-6725*
IN THE CONTINENTAL UNITED STATES
*In Maryland, call collect (301) 881-0256
between 9:00 AM and 4:30 PM

FORM FDA 25191 (3/85)

CATHETERS, OTHER [15-209]

Device: PEDIATRIC INTERNAL JUGULAR PUNCTURE KIT

Manufacturer: Arrow International Inc [1060], Hill & George Ave, Reading PA 19610

Manufacturer's Disclaimer: SEE FIRST REPORT FOR THIS MANUFACTURER

Identifier: MODEL AK04100

Problem: DEATH ALLEGEDLY ATTRIBUTED TO VESSEL PERFORATION DUE TO THE CO 20 GAUGE INDWELLING CATHETER. THE CATHETER WAS PLACED EITHER THROUGH THE INTERNAL JUGULAR OR SUBCLAVIAN VEIN.

FDA Comment: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.

Source: M.D.R. REPORT DATED 10/10/86.

Accession No.: 130408

DEFIBRILLATOR/MONITORS, BATTERY POWERED [11-129]

Device: DEFIBRILLATOR/MONITOR

Manufacturer: Hewlett-Packard Co Medical Products Group [1883], 3000 Minuteman Rd, Andover MA 01810

Manufacturer's Disclaimer: THE INFORMATION IN THIS REPORT IS SUBMITTED SOLELY TO COMPLY WITH SECTIONS 502(T) AND 519 OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND TITLE 21, CODE OF FEDERAL REGULATIONS, PART 803-MEDICAL DEVICE REPORTING. NEITHER THE SUBMISSION OF INFORMATION NOR PUBLIC RELEASE OF SUCH INFORMATION CONSTITUTES AN ADMISSION, NOR SHALL BE CONSTRUED AS AN ADMISSION, THAT A DEVICE HAS MALFUNCTIONED OR THAT A CAUSAL RELATIONSHIP BETWEEN A PRODUCT AND A DEATH OR SERIOUS INJURY EXISTS.

Identifier: MODEL 78620A CATALOG 78620

Problem: THE DEFIBRILLATOR WOULD NOT CHARGE. IT WAS LATER FOUND THAT THE BATTERY HAD FAILED. THE BATTERY WAS 6 YEARS OLD AND HAD NOT BEEN MAINTAINED ACCORDING TO THE INSTRUCTIONS IN THE OPERATING MANUAL.

Source: M.D.R. REPORT DATED 10/14/86.

Accession No.: 128634

DEFIBRILLATOR/MONITORS, BATTERY POWERED [11-129]

Device: LIFEPAK-5

Manufacturer: Physio-Control Corp Cardiovascular Div [1601], 11811 Willows Rd NE P O Box 97006, Redmond WA 98073

Manufacturer's Disclaimer: THIS INFORMATION IS COLLECTED AND REPORTED IN ACCORDANCE WITH 21 CFR 803.24. IT IS NOT AN ADMISSION OF ANY CAUSAL ASSOCIATION BETWEEN THE REPORTED EVENTS AND ANY PHYSIO-CONTROL PRODUCT.

Identifier: CATALOG 801528-02

Problem: DURING A DEFIBRILLATION ATTEMPT OF AN 80-YR-OLD MALE PATIENT THE DEFIBRILLATOR FAILED TO CHARGE. THE ATTENDING PHYSICIAN ASSOCIATED THIS MALFUNCTION WITH THE PATIENT'S DEATH. THE PARAMEDIC AT THE SCENE SAID LATER THAT HE HAD CHECKED THE DEFIBRILLATOR ONE HOUR BEFORE USE AND DETERMINED PROPER OPERATION.

Source: M.D.R. REPORT DATED 10/03/86.

Accession No.: 101682

DEFIBRILLATOR/MONITORS, BATTERY POWERED [11-129]

Device: LIFEPAK 6S

Manufacturer: Physio-Control Corp Cardiovascular Div [1601], 11811 Willows Rd NE P O Box 97006, Redmond WA 98073

Manufacturer's Disclaimer: SEE FIRST REPORT FOR THIS MANUFACTURER

Identifier: MODEL 801585-17

Problem: 78-YEAR-OLD MALE PT SUFFERED HEART FAILURE DURING TRANSPORT TO MED CTR. PT CONDITION WAS DESCRIBED AS ABDOMINAL AORTIC ANEURYSM, RENAL FAILURE, AND INTERNAL INJURY. DURING A DEFIBRILLATION ATTEMPT, THE UNIT FAILED TO CHARGE TWICE. THE UNIT WORKED ON THE THIRD ATTEMPT. PT WAS NOT RESUSCITATED.

Source: M.D.R. REPORT DATED 10/14/86.

Accession No.: 128843

DEFIBRILLATOR/MONITORS, BATTERY POWERED [11-129]

Device: LIFE PAK 6

Manufacturer: Physio-Control Corp Cardiovascular Div [1601], 11811 Willows Rd NE P O Box 97006, Redmond WA 98073

Manufacturer's Disclaimer: SEE FIRST REPORT FOR THIS MANUFACTURER

Identifier: MODEL 800270-01

Problem: A 79-YR-OLD MALE PT WAS RECEIVED IN ER COMPLAINING OF ARM PAIN AND SHORTNESS OF BREATH. THE PT THEN LOST CONSCIOUSNESS AND SEIZED. ECG ELECTRODES WERE APPLIED TO THE PT. THE MONITOR WOULD NOT TURN ON UNDER BATTERY OR AC POWER. A BACK-UP DEFIBRILLATOR AND MONITOR WERE AVAILABLE AND USED. THE PT WAS NOT RESUSCITATED.

Source: M.D.R. REPORT DATED 10/16/86.

Accession No.: 130575

DEFIBRILLATORS, IMPLANTABLE [16-652]

Device: AUTOMATIC CARDIOVERTER DEFIBRILLATOR

Manufacturer: Cardiac Pacemakers Inc Sub Eli Lilly and Co [1144], 4100 N Hamline Ave, St Paul MN 55164

Manufacturer's Disclaimer: THIS INFORMATION IS SUBMITTED PURSUANT TO 21 CFR SECTION 803. CPI DOES NOT CONSIDER THIS REPORT OR ITS CONTENTS TO BE AN ADMISSION THAT A CPI PRODUCT IS DEFECTIVE, OR THAT A CPI PRODUCT HAS CAUSED A DEATH OR SERIOUS INJURY.

Identifier: MODEL 1400

Problem: THE PT WAS AT HOME AND OBSERVED TO BE FINE. A SHORT TIME LATER WAS FOUND UNRESPONSIVE AND BROUGHT TO AN EMERGENCY ROOM WHERE HE WAS IN ASYSTOLE UPON ARRIVAL.

Source: M.D.R. REPORT DATED 10/03/86.

Accession No.: 128717

ELECTROCARDIOGRAPHS [11-407]

Device: MAC II

Manufacturer: Marquette Electronics Inc [1681], 8200 W Tower Ave, Milwaukee WI 53223

Manufacturer's Disclaimer: THIS REPORT IS REQUIRED BY THE MEDICAL DEVICE REPORTING REGULATIONS CONTAINED IN 21CFR 803. AS PROVIDED IN 21CFR803.24 (F), IT DOES NOT ESTABLISH ANY CAUSAL RELATIONSHIP ▶

LIFE EXPECTANCY OF EQUIPMENT

ITEM	DESCRIPTION	YEARS
Usage	8-24 Hours/Day	1
	0-8 Hours/Day	2
Movement	Some	0
	None	2
Design	Easy to use 3 or less controls	3
	Moderate to use 4-8 Controls	2
	Difficult to ue 8^+ Controls	1
Repairs Per Year	1 or less	3
	2-5	2
	Over 5	1
Cost of Repairs/Year	Less than 10% of cost	2
	11-15% of cost	1
	Over 15% of cost	0
Procurement Cost	Over $50,000.00	5
	Over $30,000.00	4
	Over $20,000.00	3
	Over $10,000.00	2
	Under $10,000.00	1

Add up all factors and that gives you the life expectancy.

EXAMPLE: Lifepak 7 Defibrillator

Usage	2
Movement	0
Design	2
Repairs/Year	3
Cost Of Repairs	1
Procurement Cost	1
TOTAL	9 years

NOTE: 7 Years is the allowable Depreciation by General Accounting Office

WHAT YOU DON'T KNOW ABOUT DEFIBRILLATORS:
Results of an Investigation into
Defibrillator Maintenance and Operation
Thursday, April 7

Evaluation of Program

What information from this program was most helpful/applicable to you and your work and general knowledge of this field?

____

____

What was the least helpful part of this seminar?______________________________

____

What are your comments about the location, timing, format, etc.?

____

____

Please comment on future programs--those needed immediately and those needed next year.______________________________

____

What are areas where training is NOT needed?______________________________

____

Please check all that apply to you:

( ) Ambulance Operations Manager

( ) Biomedical Engineer

( ) Equipment Maintenance Manager

( ) Hospital Administrator

( ) Nurse

( ) Paramedic

( ) Physician

( ) Other:______________________________

Evaluation of Speakers

PAUL ZOLL: Historical Background of Defibrillator

The content was: ( ) too technical ( ) too basic ( ) about right

Speaker knowledge of subject was: ( ) adequate ( ) inadequate

Handouts and/or audiovisuals from this presentation were:
( ) not used ( ) useful ( ) not useful

I expect to use about _______% of the information presented.

Other comments on this presenter's style or content:___________________

____

PHILLIP PIASECKI: National Overview of Defibrillator Studies

The content was: ( ) too technical ( ) too basic ( ) about right

Speaker knowledge of subject was: ( ) adequate ( ) inadequate

Handouts and/or audiovisuals from this presentation were:
( ) not used ( ) useful ( ) not useful

I expect to use about _______% of the information presented.

Other comments on this presenter's style or content:___________________

____

JAMES NICKERSON: Overview of Massachusetts Defibrillator Investigation

The content was: ( ) too technical ( ) too basic ( ) about right

Speaker knowledge of subject was: ( ) adequate ( ) inadequate

Handouts and/or audiovisuals from this presentation were:
( ) not used ( ) useful ( ) not useful

I expect to use about _______% of the information presented.

Other comments on this presenter's style or content:___________________

____

KENNETH LEARY: Findings/Recommendations of the Massachusetts Study

The content was: ( ) too technical ( ) too basic ( ) about right

Speaker knowledge of subject was: ( ) adequate ( ) inadequate

Handouts and/or audiovisuals from this presentation were:
( ) not used ( ) useful ( ) not useful

I expect to use about _______% of the information presented.

Other comments on this presenter's style or content:___________________

____

DAVID HARRINGTON: Findings/Recommendations of the Massachusetts Study
The content was: ( ) too technical ( ) too basic ( ) about right

Speaker knowledge of subject was: ( ) adequate ( ) inadequate

Handouts and/or audiovisuals from this presentation were:
( ) not used ( ) useful ( ) not useful

I expect to use about _______% of the information presented.

Other comments on this presenter's style or content:__________________

____

PATRICIA KELLY: Future Technology: Clinical Applications
The content was: ( ) too technical ( ) too basic ( ) about right

Speaker knowledge of subject was: ( ) adequate ( ) inadequate

Handouts and/or audiovisuals from this presentation were:
( ) not used ( ) useful ( ) not useful

I expect to use about _______% of the information presented.

Other comments on this presenter's style or content:__________________

____

Evaluation of Program Objectives

Did this program provide enough information to enable you to:

	YES	NO
Describe how and why the defibrillator was invented.		
Name the states and kinds of health care organizations that participated in this study.		
Outline how Massachusetts DHCQ set up and conducted this defibrillator study.		
Describe at least two problems with defibrillators this investigation uncovered.		
Summarize the major findings of the Massachusetts study.		
Describe the the study's recommendations for defibrillator maintenance and operation.		
Outline the trends in research and development of defibrillators.		
Describe the clinical applications for new equipment.		

Thank you!

APPENDIX D: FIGURES

Figure 1

PARAMEDIC AMBULANCE SERVICES SURVEYED

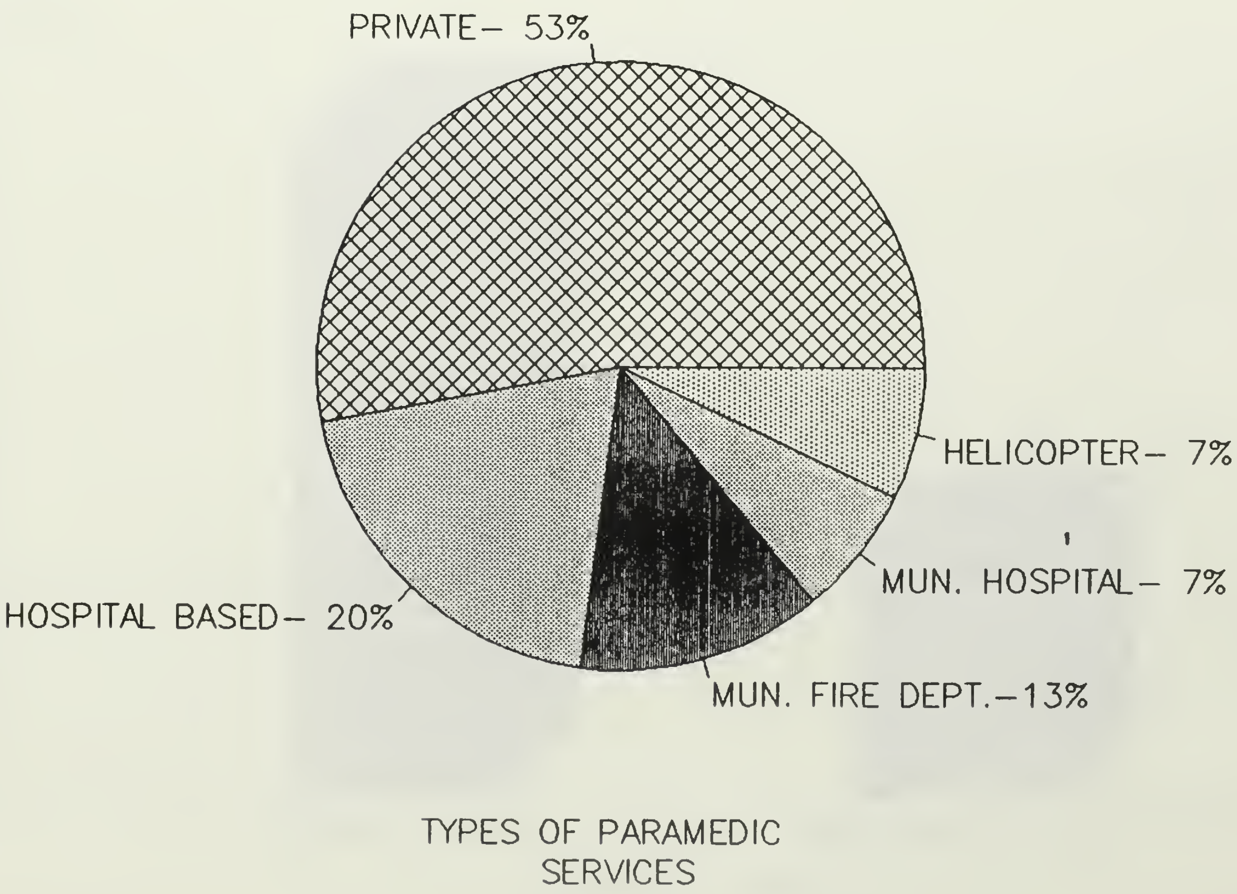


Figure 2

DEFIBRILLATOR UNITS SURVEYED

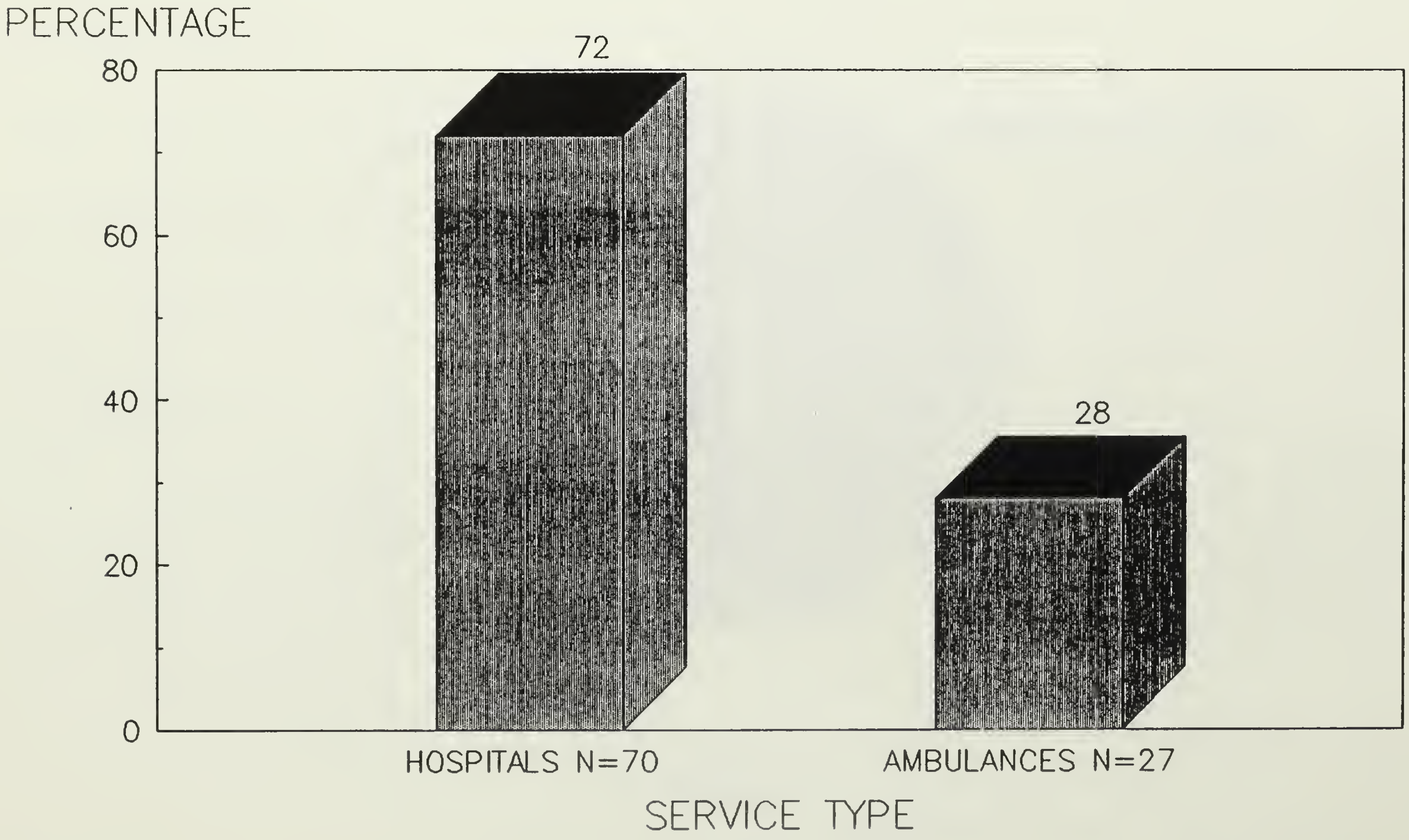


Figure 3

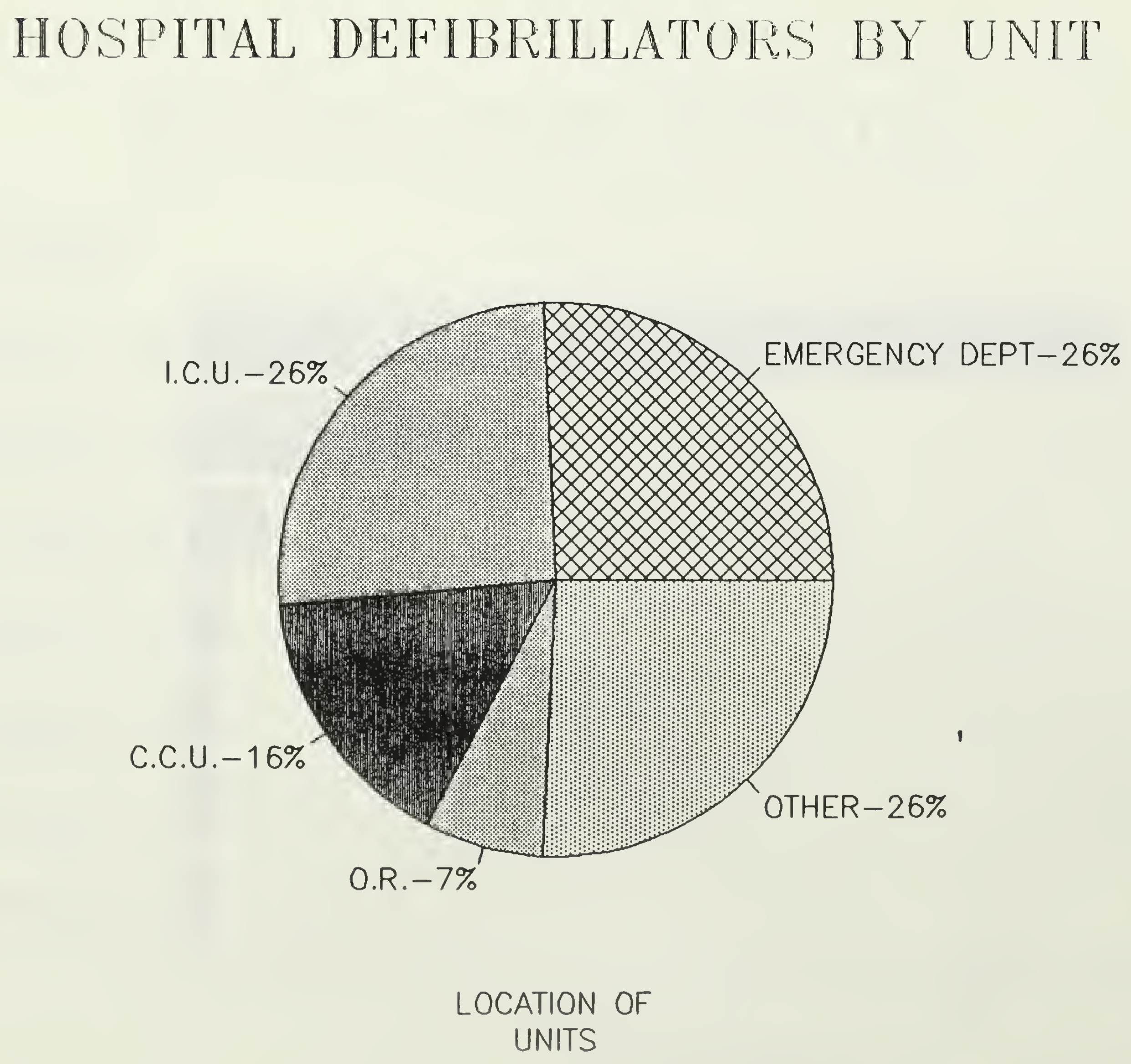

HOSPITAL DEFIBRILLATORS BY UNIT
I.C.U.–26%
EMERGENCY DEPT–26%
C.C.U.–16%
OTHER–26%
O.R.–7%
LOCATION OF UNITS

Figure 4

DEFIBRILLATORS SURVEYED

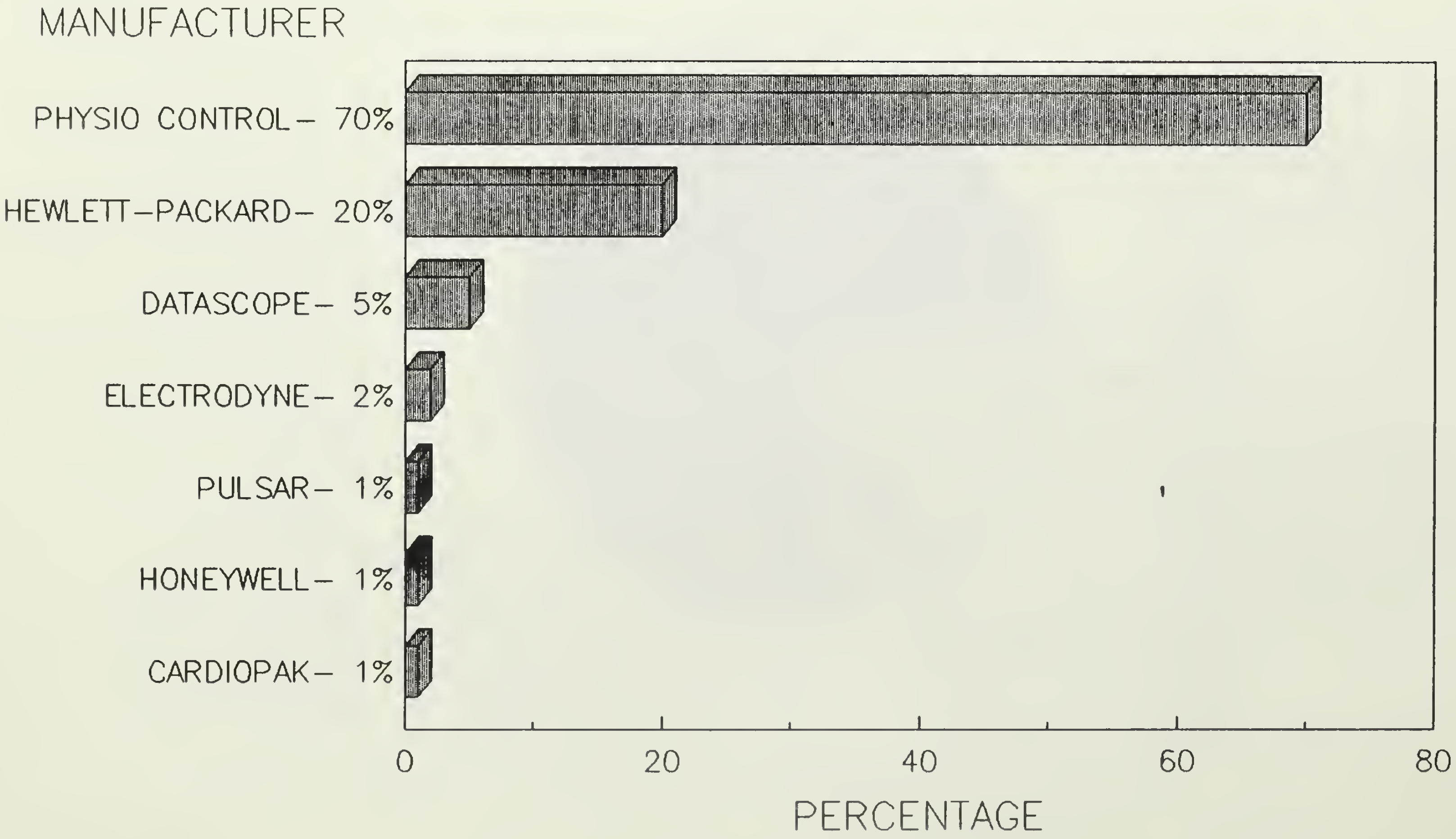
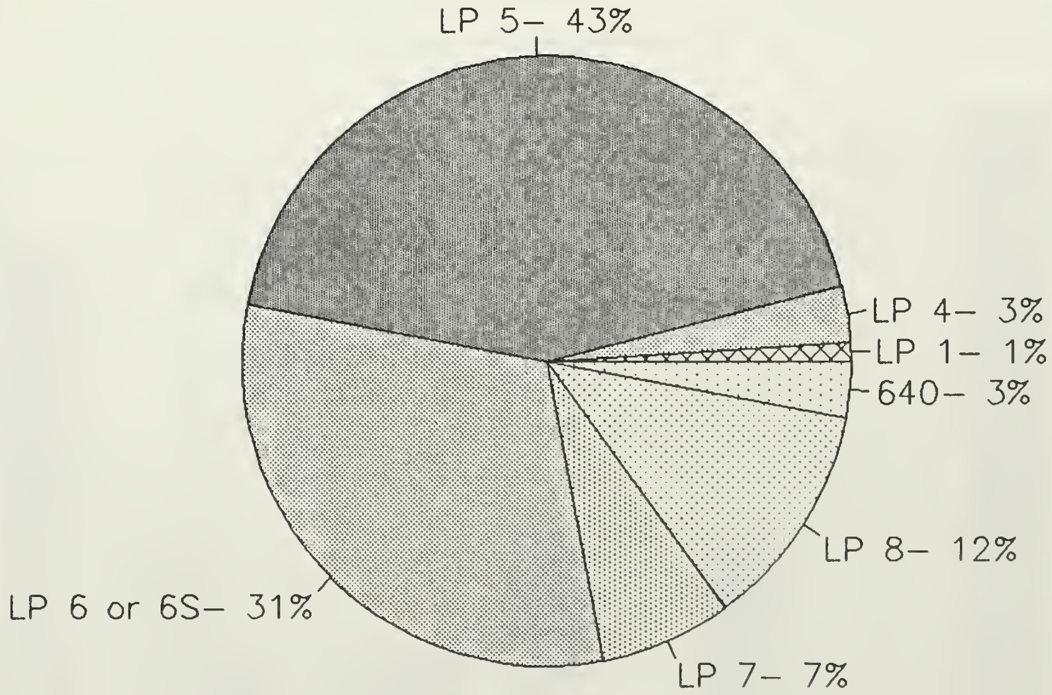


Figure 5

PHYSIO CONTROL MODELS SURVEYED



LP = LIFEPAK

Figure 6

FREQUENCY OF CONTINUING EDUCATION BY
HOSPITALS AND AMBULANCE SERVICES

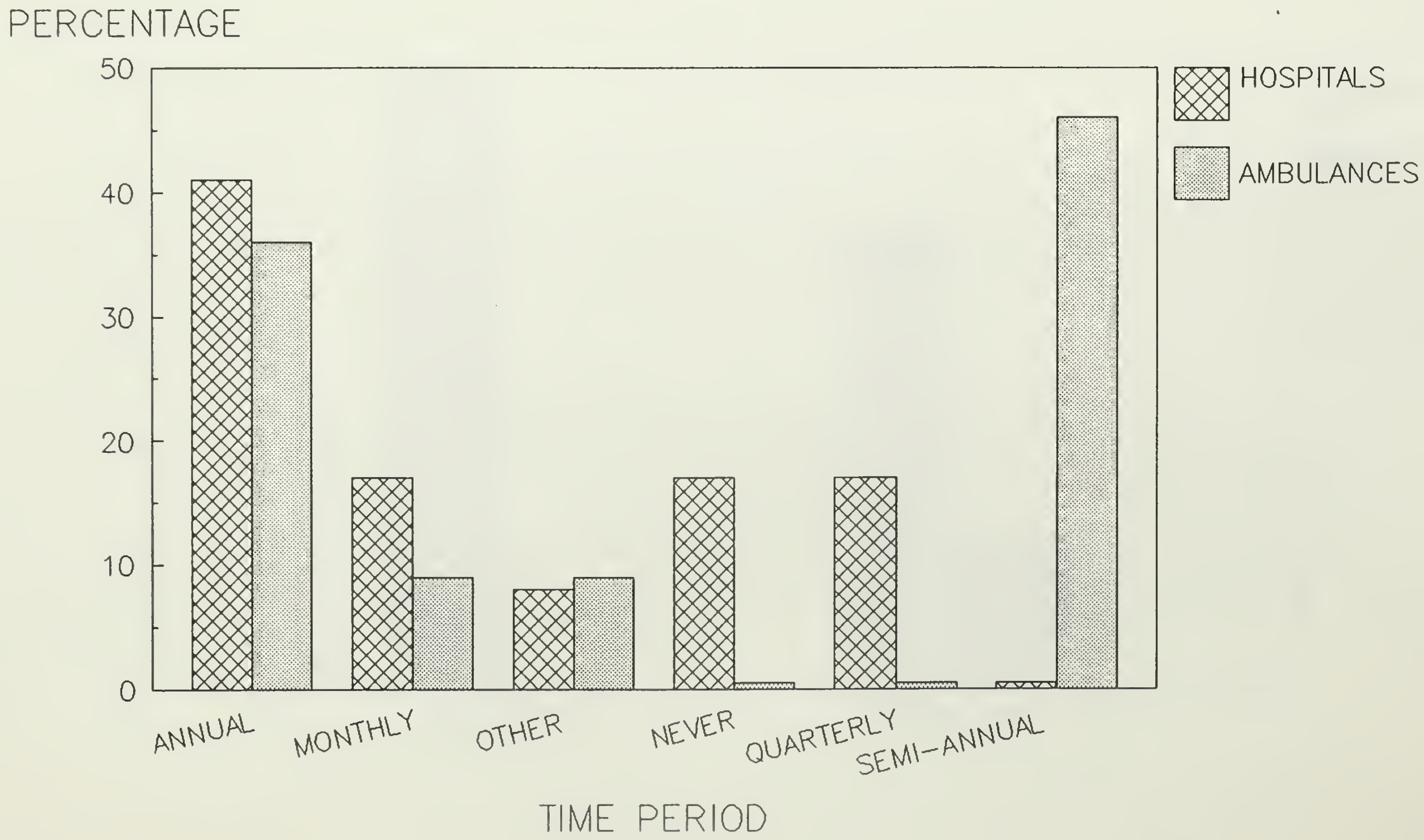


Figure 7

PREVENTATIVE MAINTENANCE PROVIDED BY
HOSPITALS AND AMBULANCE SERVICES

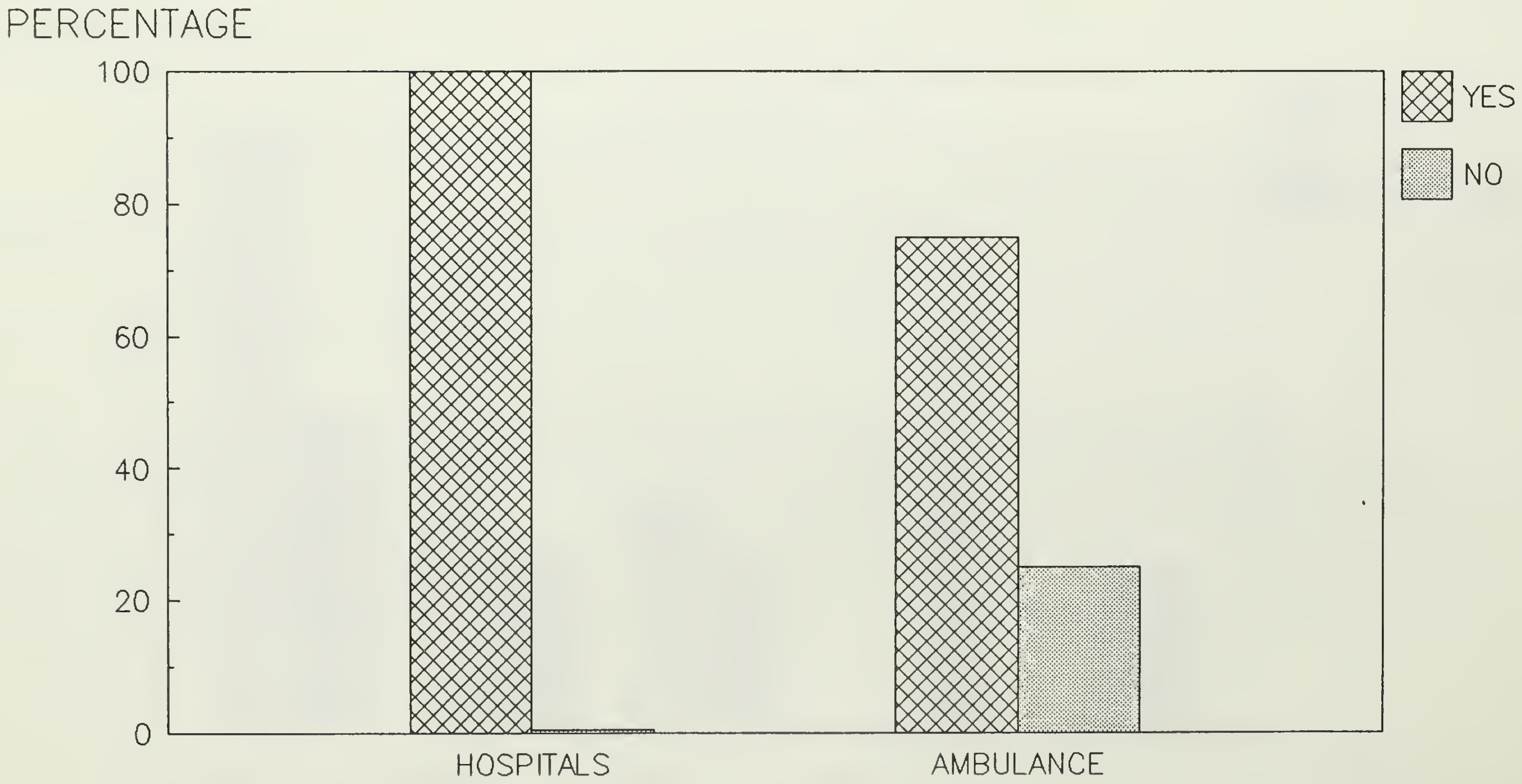


Figure 8

FREQUENCY OF PREVENTATIVE MAINTENANCE AT
HOSPITALS AND AMBULANCE SERVICES

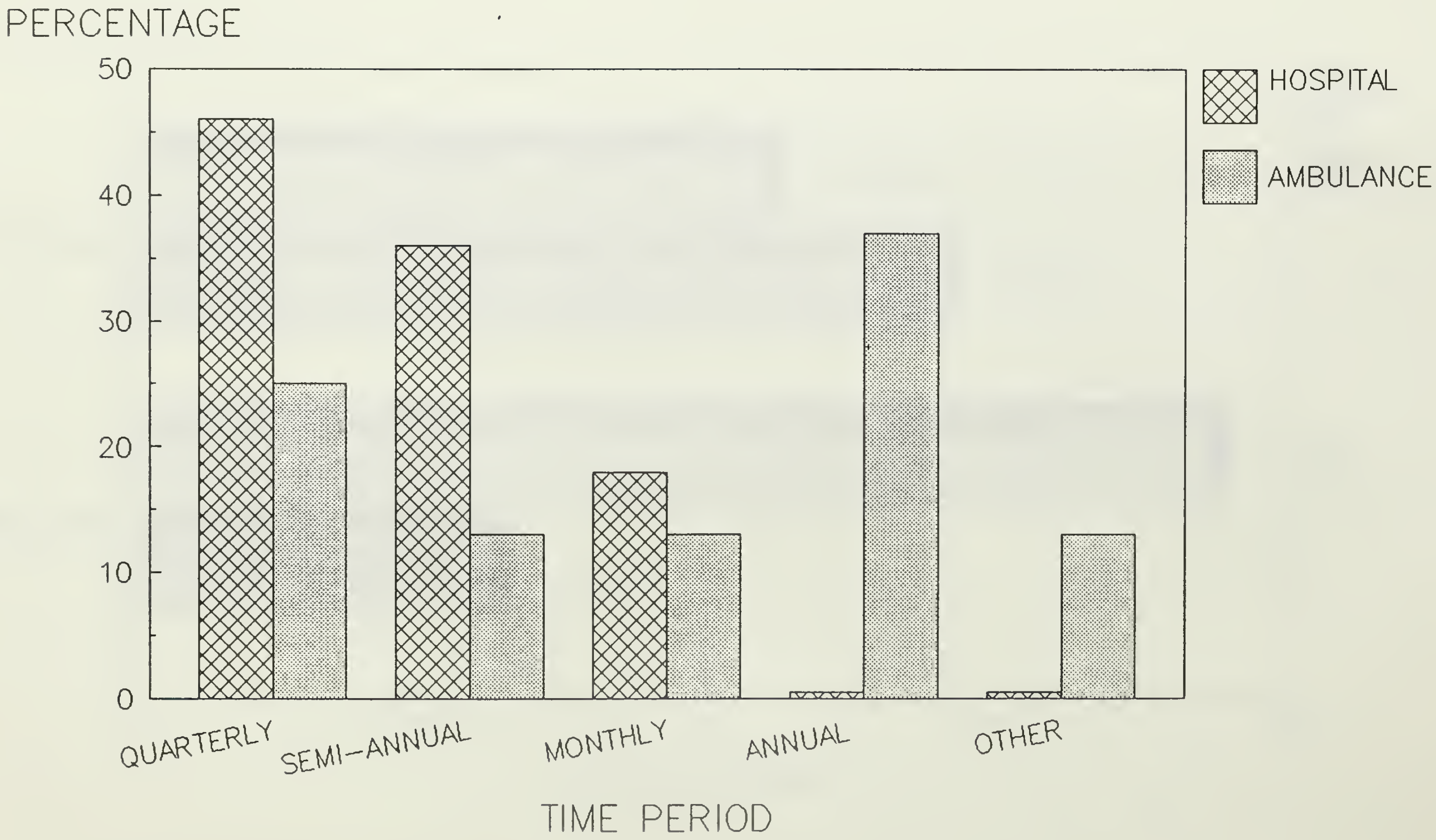


Figure 9

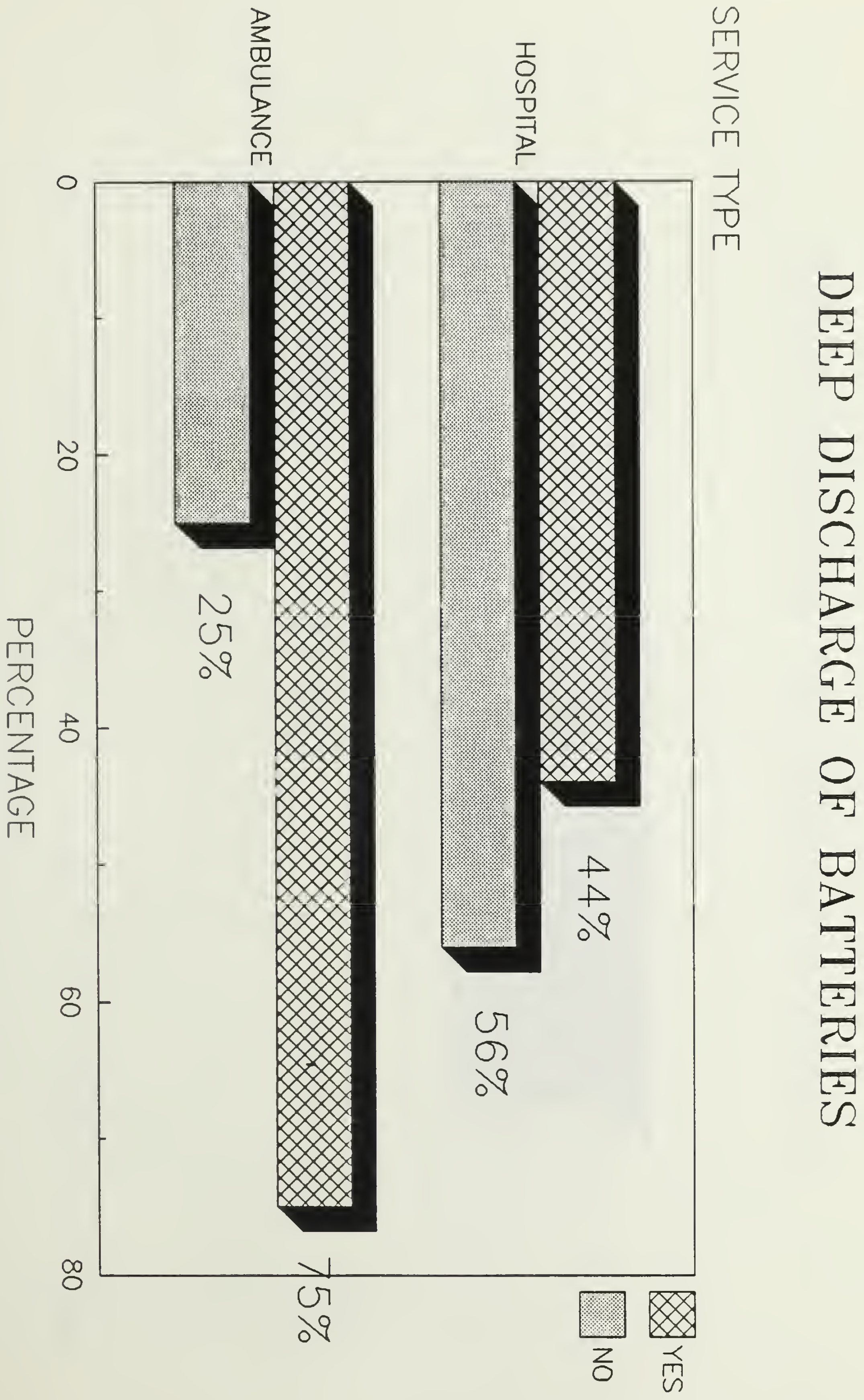

DEEP DISCHARGE OF BATTERIES
SERVICE TYPE
HOSPITAL
AMBULANCE
44%
56%
25%
75%
0
20
40
60
80
PERCENTAGE
YES
NO

Figure 10

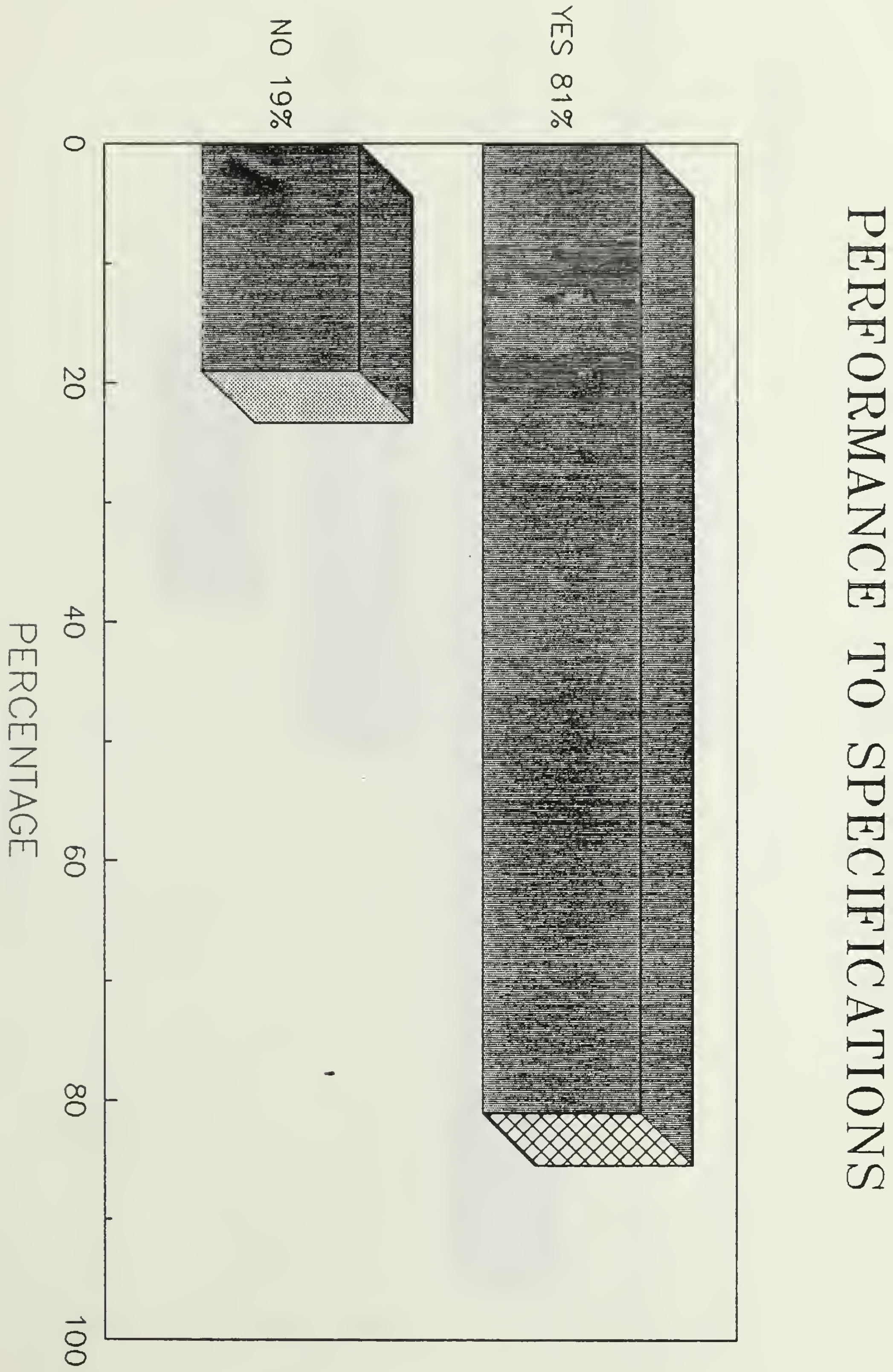
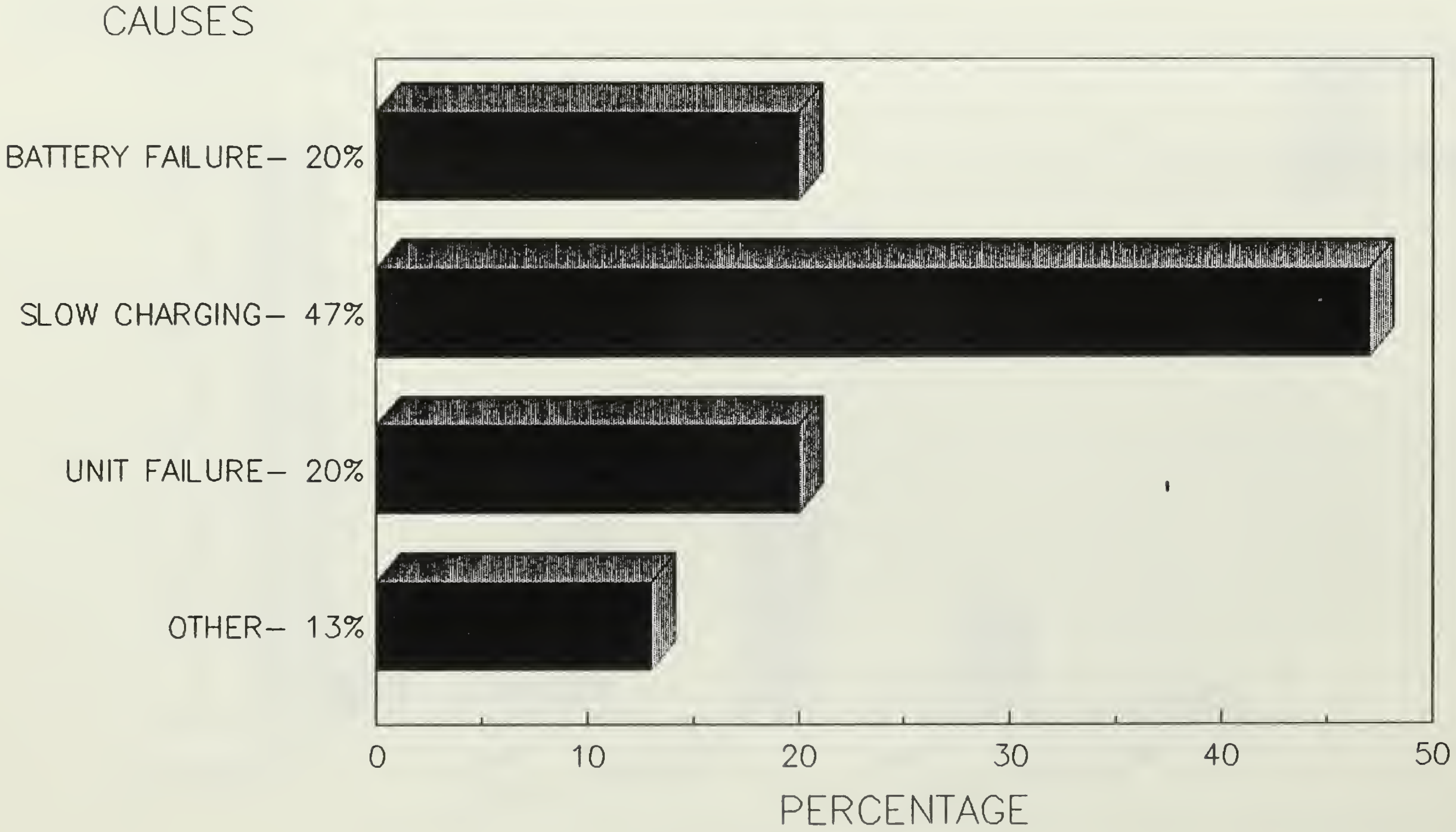

PERFORMANCE TO SPECIFICATIONS
YES 81%
NO 19%
0
20
40
60
80
100
PERCENTAGE

Figure 11



DEFIBRILLATOR FAILURE

Figure 12

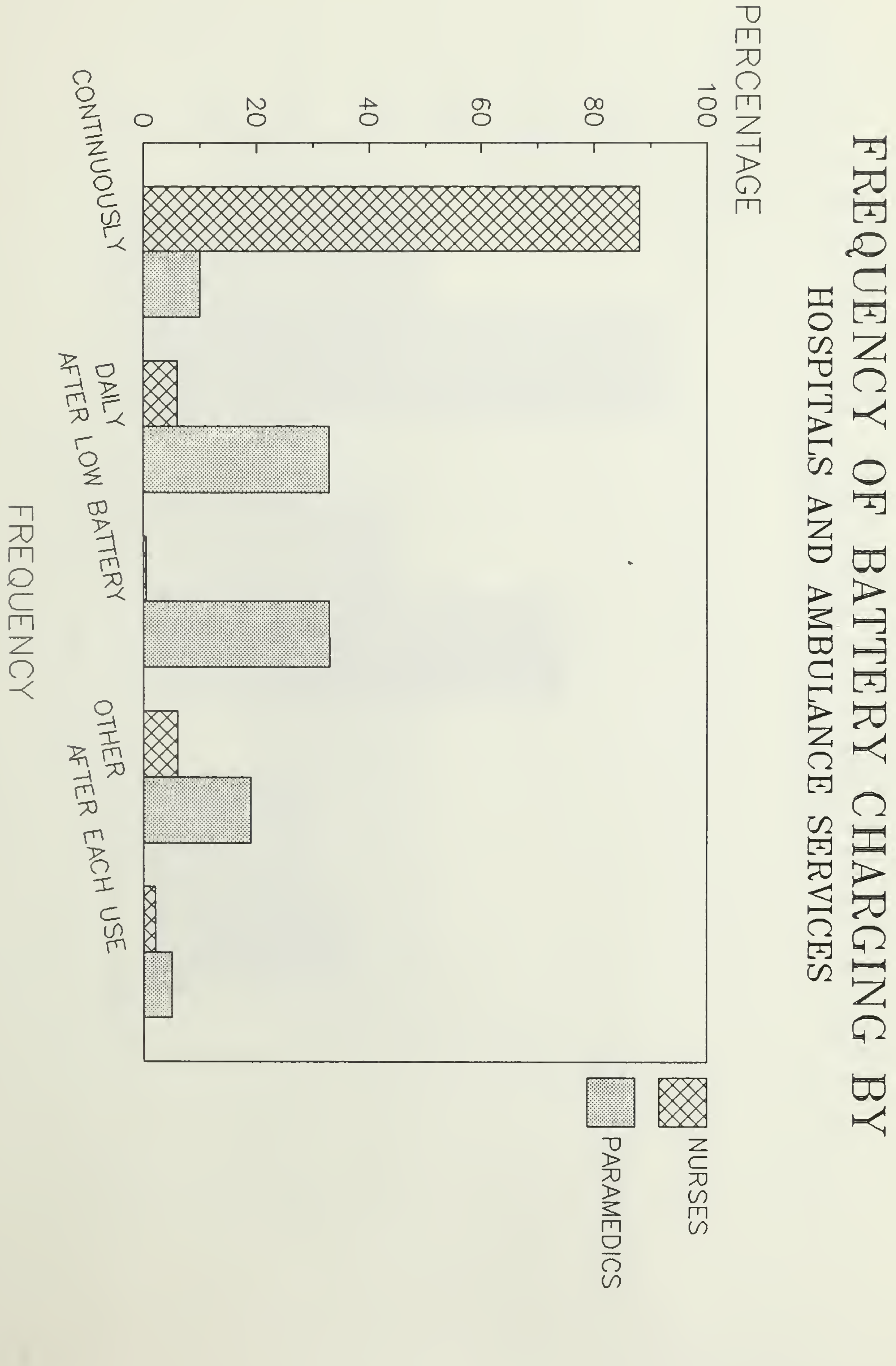
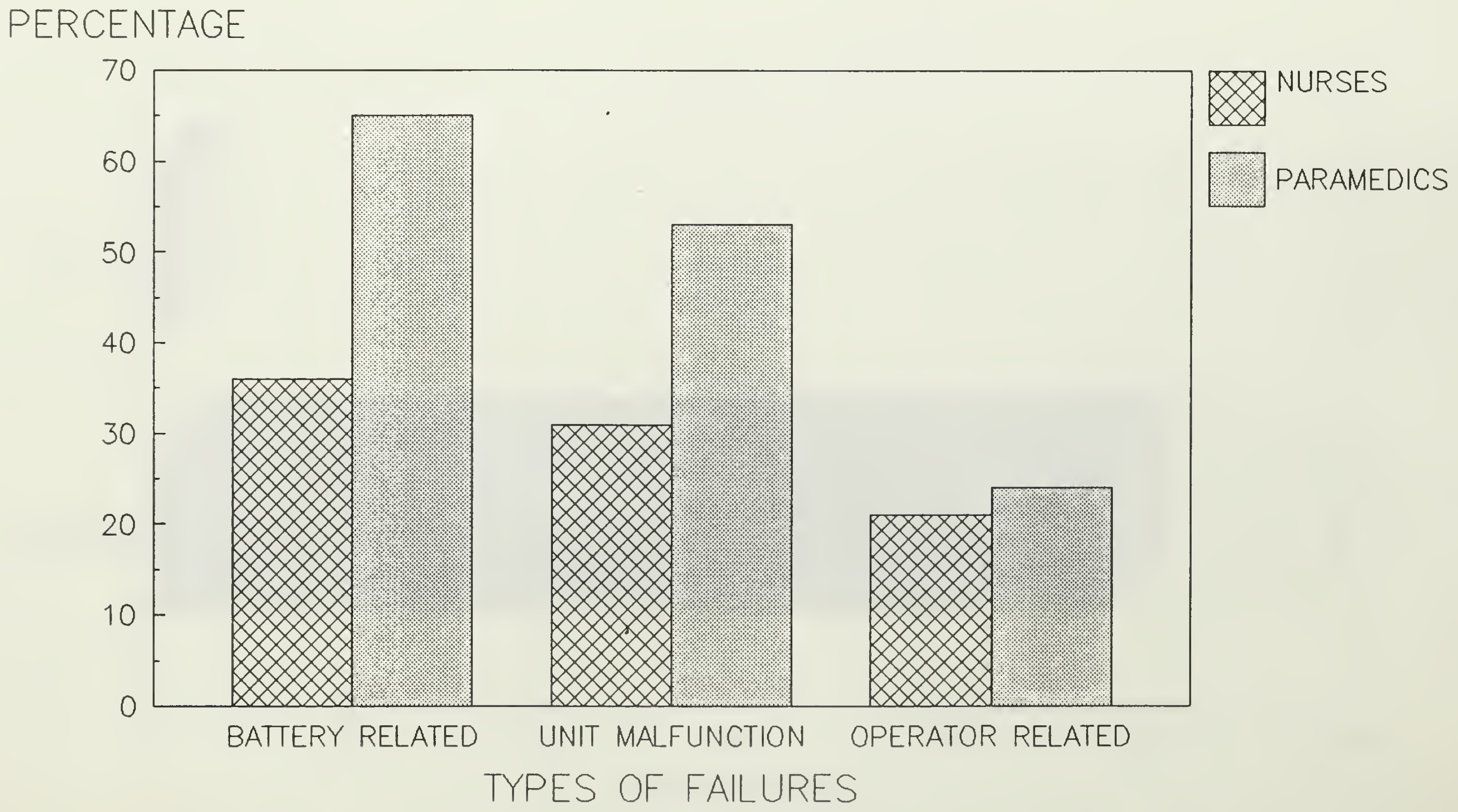

FREQUENCY OF BATTERY CHARGING BY
HOSPITALS AND AMBULANCE SERVICES
PERCENTAGE
100
80
60
40
20
0
CONTINUOUSLY
DAILY
AFTER LOW BATTERY
OTHER
AFTER EACH USE
FREQUENCY
NURSES
PARAMEDICS

Figure 13



TYPES OF FAILURES REPORTED BY
NURSES AND PARAMEDICS

Figure 14

PROBLEMS WITH SYNCHRONIZED CARDIOVERSION